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Presidential Documents

Title 3—

The President

Proclamation 5845 of August 9, 1988

National Neighborhood Crime Watch Day, 1988

By the President of the United States of America

A Proclamation

Last year, crime left its mark on one in four American homes, a sobering reminder that, despite recent heartening progress against criminals and the causes of crime, particularly drug abuse, much remains to be done to ensure for ourselves and our children the safety of our homes, our neighborhoods, and our communities. It is an unfortunate fact that the scourge of crime continues to occupy the head of the list of national problems crying out for immediate action.

Those who have experienced the pain, the loss, the sense of violation and frustration that accompany crime know that defeating it requires more than tougher laws and surer punishments—though tougher and surer they are. Truly effective law enforcement demands our reliance on one of our great historical strengths as a Nation: the willingness of our people to band freely together, in local communities, in defense of lives, homes, and property.

Local crime watch committees, in cooperation with law enforcement officers and the appropriate government agencies, can make a real difference in crime rates. As McGruff the anti-crime dog, the familiar national symbol of crime prevention, would put it: They take a bite out of crime. But the benefits of such citizen groups do not stop there: Their work teaches children respect for law, reinforces community values, and encourages the kind of individual responsibility that makes for healthy, creative neighborhoods peopled by safer and happier citizens.

The growth of these committees is truly encouraging. Today over 19 million Americans participate in neighborhood watch programs, keeping an eye out for crime near their homes, reporting suspicious activity to the police, and providing escorts to elderly or vulnerable citizens.

And for the last several years, millions of Americans have joined in the highly visible "National Night Out," an evening sponsored by the National Association of Town Watch in which families spend the period from 8 o'clock to 9 o'clock p.m. on their front porch or lawn as a way of saying to potential criminal predators: "You had better think twice, because in this community neighbors look out for each other." This worthwhile event has been extended this year to 10 o'clock.

The Congress, by Senate Joint Resolution 294, has designated August 9, 1988, as "National Neighborhood Crime Watch Day" and has authorized and requested the President to issue a proclamation in observance of this event.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim August 9, 1988, as National Neighborhood Crime Watch Day.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of August, in the year of our Lord nineteen hundred and eighty-eight, and of the Independence of the United States of America the two hundred and thirteenth.

Ronald Reagan

[FR Doc. 88-18396
Filed 8-10-88; 4:27 pm]
Billing code 3195-01-M

Rules and Regulations

Federal Register
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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 week.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 910

[Lemon Reg. 626]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: Regulation 626 establishes the quantity of fresh California-Arizona lemons that may be shipped to market at 310,000 cartons during the period August 14 through August 20, 1988. Such action is needed to balance the supply of fresh lemons with market demand for the period specified, due to the marketing situation confronting the lemon industry.

DATES: Regulation 626 (§ 910.926) is effective for the period August 14 through August 20, 1988.

FOR FURTHER INFORMATION CONTACT: Raymond C. Martin, Section Head, Volume Control Programs, Marketing Order Administration Branch, F&V, AMS, USDA, Room 2523, South Building, P.O. Box 96456, Washington, DC 20090-6456; telephone: (202) 447-5697.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Executive Order 12291 and Departmental Regulation 1512-1 and has been determined to be a "non-major" rule under criteria contained therein..

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

The purpose of the RFA is to fit regulatory action to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Agricultural Marketing Agreement Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

This regulation is issued under Marketing Order No. 910, as amended (7 CFR Part 910) regulating the handling of lemons grown in California and Arizona. The order is effective under the Agricultural Marketing Agreement Act (the "Act," 7 U.S.C. 601-674), as amended. This action is based upon the recommendation and information submitted by the Lemon Administrative Committee and upon other available information. It is found that this action will tend to effectuate the declared policy of the Act.

This regulation is consistent with the marketing policy for 1988-89. The committee met publicly on August 9, 1988, in Los Angeles, California, to consider the current and prospective conditions of supply and demand and unanimously recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports that the demand for lemons is fairly good.

Pursuant to 5 U.S.C. 553, it is further found that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice and engage in further public procedure with respect to this action and that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared purposes of the Act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary, in order to effectuate the declared purposes of the Act, to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 910

Marketing agreements and orders, California, Arizona, Lemons.

For the reasons set forth in the preamble, 7 CFR Part 910 is amended as follows:

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

1. The authority citation for 7 CFR Part 910 continues to read as follows:

Authority: Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

2. Section 910.926 is added to read as follows:

Note.— This section will not appear in the Code of Federal Regulations.

§ 910.926 Lemon Regulation 626.

The quantity of lemons grown in California and Arizona which may be handled during the period August 14, 1988, through August 20, 1988, is established at 310,000 cartons.

Dated: August 10, 1988.

Robert C. Keeney,
Deputy Director, Fruit and Vegetable Division.

[FR Doc. 88-18382 Filed 8-11-88; 8:45 am]

BILLING CODE 3410-02-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 171

Revision of Fee Schedule

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim rule.

SUMMARY: The NRC is amending its regulations, on an interim basis, to revise the annual charges for licensed power reactors for Fiscal Year 1988 (FY88). The interim rule raises the ceiling on collection of annual fees to an amount that will approximate, but not be less than 45 percent of the Commission's budget. The increase of 12 percent will be apportioned among the licensed power reactors in the same manner as under the current fee schedule regulations. This action is necessary to provide for the timely collection of fees as required by recently enacted legislation.

EFFECTIVE DATE: September 12, 1988.

FOR FURTHER INFORMATION CONTACT: Lee Hiller, Assistant Controller, U.S. Nuclear Regulatory Commission,

Washington, DC 20555, telephone (301) 492-7351.

SUPPLEMENTARY INFORMATION: On June 27, 1988, the NRC published in the **Federal Register** (53 FR 24077) a proposed rule that would amend its regulations in 10 CFR Parts 170 and 171. This revision is necessary to both update the current fees and to implement recently enacted legislation. The proposed amendments would: Change the hourly rate under Part 170; remove fee ceilings on certain collections under Part 170; charge for each routine and nonroutine inspection; raise the annual fee under Part 171 when necessary, based on the principle that those licensees requiring the greatest expenditure of resources should pay the greatest fee; include collections from the Department of Energy Nuclear Waste Fund in agency collections; remove the application fee and defer recovery of costs for standardized reactor designs, and remove amendment application filing fees for reactors and reactor-related (topical) reports. Most of these proposals are intended to help the NRC meet its statutorily mandated requirement to recover not less than 45 percent of its budget for each of fiscal years 1988 and 1989 through fees and other collections authorized by law. The increase in collections from 33 percent of the NRC's budget to not less than 45 percent is mandated by section 5601 of the Omnibus Budget Reconciliation Act of 1987 (OBRA-Pub. L. 100-203).

In its **Federal Register** notice on proposed amendments to 10 CFR Parts 170 and 171, the Commission requested comments on a second option for recovery of not less than 45 percent of its budget. Under that option, the Commission would not amend 10 CFR Parts 170 and 171 other than to raise the annual fee under 10 CFR Part 171 so that when added to fees collected under 10 CFR Part 170, the Commission would collect not less than 45 percent of its budget in FY88.

Several comments were received which addressed the option. They were divided about equally between those in favor and those opposed. Generally the power reactor community was opposed to the second option on the ground that it increased the annual fee for power reactors without any commensurate sharing of the mandated increase in collections to 45 percent by other licensees and applicants. On the other hand, materials licensees favored the second option for the reason that it did not increase their burden. Two power reactor licensees favored the second option, one of them as an interim measure. The bulk of the power reactor community, in opposing the second option, appeared to be viewing it as a long term option and not as a stopgap measure to meet the immediate statutory directive for collections for fiscal year 1988. In view of the balance of the comments, the Commission will not pursue the second option for fiscal year 1989 and beyond, but will proceed with amendments to both 10 CFR Parts 170 and 171. The comments do not, however, present a persuasive argument for not proceeding with the second option for fiscal year 1988 collections.

Commenters also addressed the issue of refunds for overpayment of annual fees under 10 CFR Part 171. The only comments received were from the power reactor community and are based upon reading the language in section 5601 of OBRA as imposing a 45 percent ceiling on the collections in a fiscal year. In the view of the Commission, reading the 45 percent as a ceiling is contrary to the plain language and clear meaning of the statute which requires that, "in no event shall such percentage be less than a total of 45 percent of such costs in each such fiscal year." Although the statute presents some problems of interpretation, this is not one of them. The 45 percent is clearly a floor, not a ceiling. Accordingly, the provision for refunds is removed in this interim rule. It is the intention of the Commission, however, that collections of fees for fiscal year 1988 should exceed 45 percent by only a trivial amount, if at all.

The NRC is under statutory mandate, which it cannot ignore, to collect approximately, but not less than 45 percent of its budget for FY88. Given the time necessary to review all comments, to publish a final rule, and to send out additional invoices so that collections will be received prior to the end of the fiscal year, the Commission is publishing the second option as an interim rule applicable to FY88, effective 30 days after publication. Because the Commission has received and considered public comments on the two aspects of 10 CFR Part 171 being changed by this interim final rule, there is no need to request further public comment. Accordingly, the rule is being published as a final rule without a separate and independent comment period.

The adjusted invoices based on this interim rule will be sent to licensees on approximately August 15, 1988, after the rule is published in the **Federal Register**. These invoices will be due and payable upon issuance. In accordance with current regulations, interest on the invoices will be waived if the invoices are paid within 30 days of their issuance. Licensees were notified with their April and July quarterly invoices under 10 CFR Part 171 that there would be an additional invoice, based on the new statute, in FY88.

Adoption of the second option for FY88 requires that § 171.15 be amended to reflect collections of not less than 45 percent instead of the current 33 percent ceiling on total fee collections. This interim rule will apply only to FY88 and will be superseded by a final rule after the Commission fully considers comments it received in response to its purposed revision of 10 CFR Parts 170 and 171 published in the **Federal Register** on June 27, 1988. The final rule will apply to fees for FY89.

In order to comply with OBRA, the Commission is required to collect $177 million in FY88. Based on current estimated collections under 10 CFR Part 170 of $41.3 million and anticipated total collections under 10 CFR Part 171 of $99.5 million, the Commission must collect an additional $36.2 million in order to reach the collections objective. Accordingly, the FY88 annual fee adjustment is $350,000 for each licensed power reactor. The annual fees for those plants previously granted a partial exemption for FY88 pursuant to § 171.11 will be increased in a like manner using the percentage rate used for the exemptions. Those plants totally exempted from the annual fee for FY88 are unaffected by this amendment.

The NRC's reading of the 45 percent legislative statute (section 5601 of the Omnibus Budget Reconciliation Act of 1987—Pub. L. 100-203) is that 45 percent does not represent a ceiling. Congress intended collections to be not less than 45 percent of the NRC's budgets for FY88 and FY89. Therefore, actual collections will approximate but be at least 45 percent of the Commission's budget. On this basis, the current refund provision of 10 CFR 171.21 is no longer necessary and is being removed.

Environmental Impact: Categorical Exclusion

The NRC has determined that this interim rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This interim rule contains no information collection requirements and, therefore, is not subject to the requirements of the Paperwork

Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*).

Regulatory Analysis

Section 7601 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) required the NRC, by rule, to establish an annual charge for regulatory services provided to its applicants and licensees, that when added to other amounts collected, equaled up to 33 percent of Commission costs in providing those services. Section 5601 of the Omnibus Budget Reconciliation Act of 1987 requires that the NRC, for the fiscal years 1988 and 1989, increase the moneys collected pursuant to section 7601 and other authority to not less than 45 percent of the Commission's costs. In order to accomplish this statutory requirement, the NRC, as an interim measure, is amending 10 CFR 171.15 (c) and (d) by revising the figure 33 percent to a target of 45 percent.

This interim rule will not have significant impacts on state and local governments and geographical regions; on health, safety, and the environment; or, create substantial costs to licensees, the NRC, or other Federal agencies. The foregoing discussion constitutes the regulatory analysis for this interim rule.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 650(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this interim rule and, therefore, that a backfit analysis is not required for this interim rule, because this amendment is mandated by 31 U.S.C. 9701 and 7601, Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99-272, 100 Stat. 146), as amended by section 5601, Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203, 101 Stat. 1330).

List of Subjects in 10 CFR Part 171

Annual charges, Nuclear power plants and reactors, Penalty.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 171.

PART 171—ANNUAL FEE FOR POWER REACTOR OPERATING LICENSES

1. The authority citation for Part 171 is revised to read as follows:

Authority: Sec. 7601, Pub. L. 99-272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100-203, 101 Stat. 1330, sec. 301, Pub. L. 92-314, 86 Stat. 222 (42 U.S.C. 2201(w)); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 171.15 [Amended]

2. In § 171.15, paragraph (e) is removed and paragraphs (c) and (d) are amended by revising the percentages specified as "33" and ".33," respectively, to read "45" and ".45."

§ 171.21 [Removed]

3. Section 171.21 is removed.

Dated at Rockville, Maryland this 8th day of August 1988.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 88-18284 Filed 8-11-88; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 88-ASW-35; Amdt. 39-5995]

Airworthiness Directives; Messerschmitt-Bolkow-Blohm GmbH Model BO-105, BO-105LS, and BK-117 Series Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action publishes in the **Federal Register** and makes effective as to all persons an amendment adopting a new airworthiness directive (AD) which was previously made effective as to all known U.S. owners and operators of certain MBB Model BO-105, BO-105LS, and BK-117 series helicopters by individual letters. The AD requires initial and recurring inspections for cracks at the junction of the bolt head and shank. The AD was needed to prevent failure of the bolt which could result in possible loss of control of the main rotor blade and subsequent loss of the helicopter.

DATES: *Effective Date:* August 26, 1988, as to all persons except those persons to whom it was made immediately effective by priority letter AD No. 87-09-03, issued May 7, 1987, which contained this amendment.

Compliance: As indicated in the body of the AD.

ADDRESSES: The applicable service information may be obtained from MBB Helicopter Corporation, P.O. Box 2349, West Chester, Pennsylvania 19380. A copy of each document supporting the AD is contained in the Rules Docket, Office of the Regional Counsel, Federal Aviation Administration, Southwest Region, Room 158, Building 3B, 4400 Blue Mound Road, Fort Worth, Texas.

FOR FURTHER INFORMATION CONTACT: Samuel E. Brodie, Department of Transportation, Rotorcraft Standards Staff, ASW-110, Fort Worth, Texas 76193-0110, telephone (817) 624-5116.

SUPPLEMENTARY INFORMATION: On May 7, 1987, priority letter AD No. 87-09-03 was issued and made effective immediately as to all known U.S. owners and operators of certain MBB Model BO-105, BO-105LS, and BK-177 series helicopters. The AD required initial and recurring inspections on main rotor secondary blade bolts. The AD was prompted by the reports of four recent bolt failures.

Since it was found that immediate corrective action was required, notice and public procedure thereon were impracticable and contrary to public interest, and good cause existed to make the AD effective immediately by individual letters issued May 7, 1987, to all known U.S. owners and operators of certain MBB Model BO-105, BO-105LS, and BK-177 series helicopters. These conditions still exist and the AD is hereby published in the **Federal Register** as an amendment to § 39.13 of Part 39 of the Federal Aviation Regulations to make it effective as to all persons.

The regulations set forth in this amendment are promulgated pursuant to the authority in the Federal Aviation Act of 1958, as amended (49 U.S.C. 1301, *et seq.*), which statute is construed to preempt state law regulating the same subject. Thus, in accordance with Executive Order 12612, it is determined that such regulations do not have federalism implications warranting the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Executive Order 12291 with respect to this rule since the rule must be issued immediately to correct

an unsafe condition in aircraft. It has been further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, when filed, may be obtained from the Regional Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation Safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 1354(a); 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new AD:

Messerschmitt-Bolkow-Blohm GMBH: Applies to Model BO-105, BO-105LS, and BK-117 series helicopters certificated in any category with main rotor blade secondary bolt P/N's 105-14101.35, 105-14101.79, 105-14101.11, and 105-141021.05 installed.

Compliance is required as indicated, unless already accomplished.

To prevent failure of the secondary main rotor blade retention bolt and possible loss of control or the main rotor blade, accomplish the following:

(a) Inspect all bolts having more than 100 hours' time in service for cracks at the junction of the head and shank using a magnetic particle inspection or a dye penetrant inspection method prior to further flight. If the dye penetrant inspection method is used, bolts with solid film lubricant coating shall have the coating removed in the affected area (to approximately 5 MM below the bolt head) using Scotch Brite or equivalent. Use MEK or equivalent to clean the surface prior to dye checking. Coated crack-free bolts need not be recoated prior to reinstallation.

(b) Inspect bolts with less than 100 hours' time is service in accordance with paragraph (a) prior to accumulating 100 hours' time in service.

(c) If cracks are found, remove bolt from service and replace with an airworthy bolt prior to further flight.

(d) Conduct the inspection of paragraph (a) at intervals not to exceed 100 hours' time in service since last inspection.

(e) Reinstall bolts in accordance with the following instructions. Lubricate crack-free bolts (per MBB Maintenance Manual) with Molykte BR2 (MBB Maintenance Manual item CM-102) or Aeroshell grease #22 (MBB Maintenance Manual item CM-101) and install per the applicable MBB Maintenance Manual with the following exceptions:

(1) Make certain that no lubricant is on the threaded area of the bolt;

(2) Before installing the nut, lightly tap the head of the bolt with a plastic or rubber mallet to seat the bolt in the hole;

(3) Install nut, and torque to 70-90 inch pounds (8-11 Newton meters); and

(4) If required to install cotter pin, back off the nut to next available cotter pin hole, and install cotter pin.

(f) Upon request, an alternate means of compliance which provides an equivalent level of safety with the requirements of this AD may be used when approved by the Manager, Aircraft Certification Division, Department of Transportation, Federal Aviation Administration, Fort Worth, Texas 76193-0100.

(g) Special flight permits may be issued in accordance with Sections 21.197 and 21.199 to operate helicopters to a base for the accomplishment of inspections required by this AD.

This amendment become effective August 26, 1988, as to all persons except those persons to whom it was made immediately effective by priority letter AD No. 87-09-03, issued May 7, 1987, which contained this amendment.

Issued in Washington, DC, on August 3, 1988.

M.C. Beard,

Director, Office of Airworthiness.

[FR Doc. 88-18269 Filed 8-11-88; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Under Secretary of the Navy has determined that USS PHILIPPINE SEA (CG-58) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special function as a naval cruiser. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: July 29, 1988.

FOR FURTHER INFORMATION CONTACT: Captain P.C. Turner, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332-2400. Telephone number: (202) 325-9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the Under Secretary of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS PHILIPPINE SEA (CG-58) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS, Annex I, section 3(a), pertaining to the location of the forward masthead light in the forward quarter of the ship, the placement of the after masthead light, and the horizontal distance between the forward and after masthead lights, without interfering with its special functions as a naval cruiser. The Under Secretary of the Navy has also certified that the above-mentioned lights are located in closet possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR Parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), Vessels.

Accordingly, 32 CFR Part 706 is amended as follows:

PART 706—[AMENDED]

1. The authority citation for 32 CFR Part 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706.2 [Amended]

2. Table Five of § 706.2 is amended by adding the following vessel:

Vessel	Number	Forward masthead light less than the required height above hull. Annex I, sec. 2(a)(i)	Aft masthead light less than 4.5 meters above forward masthead light. Annex I, sec. 2(a)(ii)	Masthead lights not over all other lights and obstructions. Annex I, sec. 2(f)	Vertical separation of masthead lights used when towing less than required by Annex I, sec. 2(a)(i)	Aft masthead lights not visible over forward light 1,000 meters ahead of ship in all normal degrees of trim. Annex I, sec. 2(b)	Forward masthead light not in forward quarter of ship. Annex I, sec. 3(a)	After masthead light less than 1 ship's length aft of forward masthead light. Annex I, sec. (3)(a)	Percentage horizontal separation attained.
USS PHILIPPINE SEA	CG-58						X	X	38

Date: July 29, 1988.
Approved:
H. Lawrence Garrett, III,
Under Secretary of the Navy.
[FR Doc. 88-18247 Filed 8-11-88; 8:45 am]
BILLING CODE 3810-AE-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL-3419-9]

Approval and Promulgation of State Implementation Plans; Colorado; Alfalfa Dehydrator Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving revisions to Colorado Regulations 1 and 5 concerning existing alfalfa dehydrators which were submitted by the Governor of Colorado on July 29, 1987. The revisions reduce the visible emission limit for alfalfa dehydrators from 40% opacity to 30% opacity. Approval of these revisions, which are expected to reduce emissions of particulate matter from alfalfa dehydrators, provides for Federal enforcement.

DATES: This action will be effective on October 11, 1988, unless notice is received by September 12, 1988, that someone wishes to submit adverse or critical comments.

ADDRESSES: Copies of the revision are available for public inspection between 8:00 a.m. and 4:00 p.m. Monday through Friday at the following offices:

Environmental Protection Agency, Region VIII, Air Programs Branch, Denver Place, Suite 500, 999 18th Street, Denver, Colorado 80202.

Environmental Protection Agency, Public Information Reference Unit, Waterside Mall, 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Dale M. Wells, Air Programs Branch, Environmental Protection Agency, Denver Place, Suite 500, 999 18th Street, Denver, Colorado 80202, (303) 293-1773, (FTS) 564-1773.

SUPPLEMENTARY INFORMATION: The Colorado Air Quality Control Commission (AQCC) Regulation 1, and the recently expired Regulation 5, provided that existing alfalfa dehydration plants must operate so as not exceed to 40% opacity. These regulations were revised on January 17, 1985, and extended the 40% opacity exemption until January 1, 1987, at which time Regulation 5 terminated. Existing alfalfa dehydrators then fell under the provisions of Regulation 1. The effect of this would have been to require existing alfalfa dehydrators to meet 20% opacity limits, thus treating existing plants the same as new plants.

On January 15, 1987, the AQCC adopted a revision to the Total Suspended Particulate (TSP) State Implementation Plan (SIP) to extend Regulation 5 and require existing plants to meet a 30% opacity limit. The 30% opacity limit is expected to result in the installation of reasonably available control equipment and other measures in revising the production process in order to minimize emissions. This revision was effective on March 2, 1987. There is only one existing alfalfa dehydrating plant in Colorado; the plant is located in an area which is in attainment of the national ambient air quality standards for particulate matter.

The EPA revised the particulate matter standard on July 1, 1987 (52 FR 24634), and eliminated the TSP ambient air quality standards. The revised standard is expressed in terms of particulate matter with a nominal diameter of 10 micrometers or less (PM_{10}). However, at the State's option, EPA will continue to process TSP SIP revisions which were in process at the time the new PM_{10} standard was promulgated. (In the policy published on July 1, 1987 (p. 24679, column 2), EPA stated that it would regard existing TSP SIPs as necessary interim particulate matter plans during the period preceding the approval of State Plans specifically aimed at PM_{10}.) If the TSP SIP revision is judged to include more stringent provisions than are in the existing TSP plan, EPA's general policy would be to approve it.

EPA is approving the revisions to Regulations 1 and 5 because, although a 20% opacity limit came into effect when the 40% limit expired, there was no intention on the part of the State to require compliance with the 20% limit. Therefore, the practical result of this revision is to tighten the emission limit to 30% for alfalfa dehydrators. EPA believes these regulations will be helpful in maintaining the area in attainment of the particulate standard.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. This action will be effective 60 days from the date of the **Federal Register** unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted.

If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective October 11, 1988.

Final Action

EPA hereby approves the revisions to Regulation 1 and 5 concerning alfalfa dehydrators as part of the Colorado TSP SIP.

EPA finds good cause exists for making the action taken in this notice immediately effective because the implementation plan revisions are already in effect under State law or regulation and EPA's approval poses no additional regulatory burden.

Under 5 U.S.C. 605(b), I certify that this SIP revision will not have a significant economic impact on a

substantial number of small entities. (See 46 FR 8709.)

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 11, 1988. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

List of Subjects in 40 CFR Part 52

Air pollution control, Particulate matter, Incorporation by reference.

Note: Incorporation by reference of the State Implementation Plan for the State of Colorado was approved by the Director of the Federal Register on July 1, 1982.

Date: July 19, 1988.

Lee M. Thomas,

Administrator

Part 52 Chapter I, Title 40 of the *Code of Federal Regulations* is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7642.

Subpart G—Colorado

2. Section 52.320 is amended by adding paragraph (c)(38) to read as follows:

§ 52.320 Identification of Plan

* * * * *

(c) * * *

(38) Revisions to Regulations 1 and 5 to control emissions from alfalfa dehydrators were submitted by the Governor on July 29, 1987.

(i) Incorporation by reference

(A) Section II.A.6 and introductory text of Section III.C.2.a of Regulation 1 and Regulation 5 adopted by the Colorado Air Quality Control Commission on January 15, 1987, effective on March 2, 1987.

[FR Doc. 88–16636 Filed 8–11–88; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 52

[FRL-3421-4]

Approval and Promulgation of State Implementation Plans; Revisions to Regulation No. 3, Visibility Protection; Colorado

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rulemaking.

SUMMARY: In this action, EPA is approving the general plan requirements, monitoring strategy, and long-term strategies (LTS) for visibility protection in mandatory Class I Federal areas in a revision to the Colorado Air Quality Control Commission (AQCC) Regulation No. 3 of the Colorado State Implementation Plan (SIP). This action is a result of rulemakings on July 12, 1985, and on November 24, 1987 (52 FR 45132), at which EPA disapproved SIPs of states which failed to comply with the provisions of 40 CFR 51.302 (visibility general plan requirements), 51.305 (visibility monitoring), and 51.306 (visibility LTS). EPA also incorporated these Federal plans and regulations into the SIPs of these states.

The Governor of Colorado submitted a SIP revision for visibility protection on December 21, 1987. Review of the plan indicates that Colorado has met the criteria of 40 CFR 51.302, 51.305, and 51.306, and that these revisions will replace the Federal plans and regulations in the Colorado Visibility SIP.

DATES: This action will be effective on October 11, 1988, unless notice is received by September 12, 1988, that someone wishes to submit adverse or critical comments.

ADDRESSES: Copies of the State submittal are available for public inspection between 8:00 a.m. and 4:00 p.m., Monday through Friday, at the following locations:

Environmental Protection Agency, Region VIII, Air Programs Branch, 999 18th Street, Suite 500, Denver, Colorado 80202–2405.

Environmental Protection Agency, Public Information Reference Unit, Waterside Mall, 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Michael Silverstein, Air Programs Branch, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202–2405, (303) 293–1769, (FTS) 564–1769.

SUPPLEMENTARY INFORMATION:

Background

Section 169A of the Clean Air Act (Act), 42 U.S.C. 7491, requires visibility protection for mandatory Class I Federal areas where EPA has determined that visibility is an important value. ("Mandatory Class I Federal areas" (hereinafter Class I areas) are certain national parks, wilderness areas, and international parks, as described in section 162(a) of the Act, 42 U.S.C. 7472(a), 40 CFR 81.400–81.437.) Section 169A specifically requires EPA to promulgate regulations requiring certain states to amend their SIPs to provide for visibility protection.

On December 2, 1980, EPA promulgated the required visibility regulations in 45 CFR 80084, codified at 40 CFR 51.300 *et seq.* It required the states to submit their revised SIPs to satisfy those provisions by September 2, 1981. (See 45 FR 80091, codified in 40 CFR 51.302(a)(1).) That rulemaking resulted in numerous parties seeking judicial review of the visibility regulations. In March 1981, the court stayed the litigation, pending EPA action on related administrative petitions for reconsideration of the visibility regulations filed with the Agency.

In December 1982, the Environmental Defense Fund (EDF) filed suit in the U.S. District Court for the Northern District of California alleging that EPA failed to perform a nondiscretionary duty under section 110(c) of the Act to promulgate Visibility SIPs. A negotiated Settlement Agreement between EPA and EDF required EPA to propose to incorporate Federal regulations in states where SIPs were deficient with respect to visibility monitoring regulations (40 CFR 51.305). However, the Settlement Agreement allowed each State an opportunity to avoid Federal promulgation if it submitted a SIP by May 6, 1985. Colorado was one of the states that did not meet this deadline. Final promulgation of Federal visibility monitoring regulations for all states (including Colorado) having deficient SIPs was published on July 12, 1985 (49 FR 28544), and became effective August 12, 1985.

The Settlement Agreement between EPA and EDF also required EPA to determine the adequacy of State Visibility SIPs to meet the general plan requirements including implementation control strategies (40 CFR 51.302), integral vista protection (40 CFR 51.302–51.307), and LTS (40 CRR 51.306). The Settlement Agreement required EPA to propose and promulgate Federal Visibility SIPs (hereinafter Federal Implementation Plans (FIPs)) to remedy any deficiencies on a specified schedule. On January 23, 1986 (51 FR 3046), EPA preliminarily determined that the SIPs of 32 states (including Colorado) were deficient with respect to the mentioned visibility provisions.

The EPA and the plaintiffs negotiated revisions to the Settlement Agreement which extended the deadlines for proposing FIPs to remedy the deficiencies. Under this revised Agreement, EPA must propose and promulgate FIPs to address the

deficiencies relating to the general plan requirements and LTS, and can defer proposing and promulgating FIPs to remedy deficiencies related to impairment which the Federal Land Managers (FLMs) have certified to EPA.

On March 12, 1987 (52 FR 7802), EPA proposed to disapprove the SIPs of 32 states (including Colorado) for failing to meet the general plan and LTS requirements of 40 CFR 51.302 and 51.306, and to incorporate these Federal regulations into each state's SIP. The states were given the opportunity to avoid promulgation if they submitted SIP revisions to EPA by August 31, 1987.

On November 24, 1987, EPA disapproved SIPs for states (including Colorado) which failed to meet the requirements of 40 CFR 51.302 and 51.306. EPA also incorporated these Federal regulations into the SIPs of these states.

On December 21, 1987, Colorado submitted a SIP revision which added new section XV "Visibility" to Air Pollution Control Commission (APCC) Regulation No. 3. Included in this submittal are plans and regulations which would replace Federal provisions for visibility general plan requirements (40 CFR 51.302), monitoring (40 CFR 51.305), and LTS (40 CFR 51.306).

Colorado has chosen not to protect integral vistas from visibility impairment at this time. A subcommittee has been established to further address this issue and will recommend the need for future action. Colorado's submittal meets the requirements of 40 CFR 51.304.

Affected Areas

The following areas in Colorado are Class I areas where visibility is an important value:

Black Canyon of the Gunnison Wilderness
Eagles Nest Wilderness
Flat Tops Wilderness
Great Sand Dunes Wilderness
La Garita Wilderness
Maroon Bells-Snowmass Wilderness
Mesa Verde National Park
Mount Zirkel Wilderness
Rawah Wilderness
Rocky Mountain National Park
Weminuche Wilderness
West Elk Wilderness

General Plan Requirements

A. Requirements

The visibility regulations provide general plan requirements for the Visibility SIPs. The general plan in 40 CFR 51.302(c) requires that the SIPs include: (1) An assessment of visibility impairment and a discussion of how each element of the plan relates to the national goal; (2) emission limitations, or other control measures, representing best available retrofit technology (BART) for certain sources; (3) provisions to protect integral vistas; (4) provisions to address any existing impairment certified by the FLM; and (5) an LTS (10 to 15 years) for making reasonable progress toward the national goal.

The Colorado Visibility SIP reiterates these general plan requirements in the "Statement of Basis, Specific Statutory Authority and Purpose" with the exception of "(3) provisions to protect integral vistas". To date, Colorado has chosen not to list integral vistas.

B. Control Strategies

The regulations establish the following process for developing control strategies to remedy existing impairment. First, the State or the FLM identifies the Class I areas where visibility impairment exists. The regulations require the states to address in the SIP any impairment which has been certified at least six months prior to SIP submittal. (See 40 CFR 51.302(c)(4).)

In identifying existing facilities which cause or contribute to the visibility impairment, the regulations require the State to adopt control strategies only to remedy impairment which has been reasonably attributed to a specific source or group of sources. Although the FLMs may provide the states with a list of sources suspected of causing any existing impairment in the certification, the responsibility of identifying sources is the State's. (See 45 FR 80086, col. 3 and 40 CFR 51.302(c)(4)(i).)

The State is required to perform a BART analysis for any existing stationary facility which has been identified as causing impairment in a Class I Federal area. The State determines BART on a case-by-case basis taking into account the technology available, the costs of compliance, the energy and non-air quality environmental impacts of compliance, the remaining useful life of the source, and the degree of improvement that can be anticipated to result from the use of the controls. The State must adopt emission limitations representing BART which must be installed as expeditiously as practical, but no later than five years for SIP approval. (See 40 CFR 51.302(c)(4).)

The State is not required to adopt emission limitations representing BART if, for example, retrofit controls do not exist or are not anticipated to result in improvements in visibility. (See 45 FR 80087, col. 1.) However, if a source has not been subject to BART because control technologies do not exist and if the Administrator determines that new technologies are available which would more effectively control that pollutant, the State must reanalyze for BART at that time. (See 40 CFR 51.302(c)(4)(v).)

Under 40 CFR 51.303, sources may apply to the Administrator of EPA for exemptions from BART if they can demonstrate that their emissions do not cause "significant" visibility impairment. The concurrence of the State and the FLM must be obtained before an exemption is granted.

The regulations do not specify methods other than visual observation for characterizing visibility impairment. However, if a state is to adequately and timely address existing visibility impairment, a thorough characterization may be necessary. The EPA is aware that it, or states, may find that the impairment cannot be attributed to specific sources and therefore cannot be addressed under the existing visibility regulations. (See 52 FR 7804, Col. 1.)

A thorough characterization is important when a BART analysis is conducted so that the anticipated improvements in visibility may be estimated. The State or EPA may find that the impairment is attributable to minor stationary sources or to emissions from prescription fires. In these cases, the need for a control strategy to remedy the impairment is assessed as part of the LTS rather than BART. (See 52 FR 7804, col. 1.)

The Colorado Visibility SIP, Section XV.D. ("Existing Impairment") and the "Statement of Basis, Specific Authority and Purpose" contains provisions which address the development of control strategies. (A significant amount of detail on the development of Federal control strategies is contained in 52 FR 7802 (March 12, 1987).)

C. Assessment of Visibility Impairment

The EPA reviewed the information provided by the Department of Interior (DOI) to determine if impairment (1) appeared to occur in Colorado's Class I areas, and (2) if impairment was a type which may be traceable to specific sources. The information provided by the FLMs indicated that no Class I area in Colorado is experiencing visibility impairment which may be traceable to specific sources.

The EPA is aware that the FLMs may in the future provide additional information on this impairment which would allow EPA or a state to attribute it to a specific source. In such cases, the information would be reviewed under the procedures described above and

addressed in the periodic review of the LTS discussed below.

Monitoring Strategy

Under 40 CFR 51.305, all states with visibility protection areas are required to have a monitoring strategy for evaluating visibility in any Class I area by visual observation or other appropriate monitoring techniques. The purposes of this requirement are to generate data for evaluating visibility impairment trends, determine potential impacts on new sources, assess the effectiveness of the visibility protection program, and identify major contribution sources. These purposes can be adequately addressed by determining the background visibility in protection areas and documenting the extent of any visibility impairment that can be attributed by a source or small group of sources.

Visibility impairment is the human perception of the effects of natural or man-made conditions which reduce visual range or contrast, or coloration change. Thus, a visibility monitoring program should identify these effects, as well as differentiate man-made effects from natural conditions. The program could generate various types of data such as reports from human observers, photographs, and/or automated instruments. The minimum data collection technique that 40 CFR 51.305 requires is visual observation. However, other more objective techniques are available. (See "Interim Guidance for Visibility Monitoring", Office of Air Quality Planning and Standards, November 1980 (EPA 450/2-80-082).)

The monitoring strategy in Colorado's SIP for Class I visibility protection is based on meeting four goals: (1) Provide information for new source visibility impact analysis; (2) determine existing conditions in Class I areas and the source(s) of any certified impairment; (3) determine actual effects from the operation of new sources or modifications to major sources on nearby Class I areas; and (4) establish visibility trends in Class I areas in order to evaluate progress toward meeting the national goals of visibility protection.

Colorado will assemble and evaluate any visibility data supplied by the FLMs and collected by the State or any other appropriate source. Colorado's visibility monitoring strategy meets EPA criteria as outlined in 40 CFR 51.305.

Long-term Strategy

A. Requirements

The regulations require that the LTS be a 10 to 15 year plan for making reasonable progress toward the national goal. The LTS must cover any existing impairment that the FLM certified at least six months before plan submission. A LTS must be developed which covers each Class I area within the State and each Class I area in another state that may be affected by sources within the State. The strategy must be coordinated with existing plans and goals for a Class I area including those of the FLMs. The strategy must state with reasonable specificity why it is adequate for making reasonable progress toward the national goal. The LTS and SIP must provide for the review of the impact of new sources as required by 40 CFR 51.307. The State must consider at a minimum the following six factors in the LTS: (1) Emission reductions due to ongoing air pollution control programs; (2) additional emission limitations and schedules for compliance; (3) measures to mitigate the impacts of construction activities; (4) source retirement and replacement schedules; (5) smoke management (techniques for agricultural and forestry management purposes including such plans as currently exist within the State for these purposes); and (6) enforcement of emission limitations and control measures.

The SIP must include a statement as to why these factors were or were not addressed in developing the LTS.

The State must commit to periodic review of the SIP on a schedule not less frequent than every three years. A periodic report must be developed in consultation with the FLMs and must contain the following: (1) Progress achieved in remedying existing impairment; (2) the ability of the LTS to achieve reasonable progress toward the national goal; (3) any change in visibility conditions since the last report or since plan approval; (4) additional measures, including the need for SIP revisions, that may be necessary to achieve progress toward the national goal; (5) the progress achieved in implementing BART and meeting other schedules laid out in the LTS; and (6) the impact of any exemption granted.

B. Remedies

The existing visibility regulations are designed to address impairment which can be traced to specific sources. EPA is deferring action on such existing impairment. Therefore, the Federal LTS is limited to the prevention of future impairment. It establishes a mechanism to address any additional impairment which may be certified in the future. Although EPA intends for these discussions to be the Federal remedy, each of the states must develop their own LTS when developing their Visibility SIPs.

1. Ongoing Air Pollution Control Programs

The regulations require that each LTS provide for the review of the potential impact on visibility a new major stationary sources or major modifications in accordance with 40 CFR 51.307. The regulations further require that each SIP contains a discussion of the effect of on-going air pollution control programs on remedying existing and preventing future impairment of visibility. The Colorado Visibility SIP has met this requirement. EPA has proposed to approve the Colorado New Source Review (NSR) program for visibility protection on March 31, 1987 (52 FR 10239). EPA will approve this SIP revision during Spring 1988.

2. Smoke Management Practices

The FLMs have not specifically identified smoke from prescribed fires as a cause of impairment in the Class I areas. Colorado presently has smoke management agreements with the FLMs. Colorado will coordinate with the FLMs to ensure that the best smoke management techniques are employed. The existing agreements may be revised during the periodic LTS review process to ensure that the impacts due to smoke from prescribed burning of visibility in Class I areas are minimized.

3. Future Certifications of Impairment

Under the revised Settlement Agreement, EPA must address existing deficiencies in Visibility SIPs. Thus, EPA has only addressed the certifications of impairment in Class I areas made by the FLMs prior to June 1, 1988. The FLM has not identified impairment in the Class I areas in Colorado.

4. Existing Visibility Impairment

Since the EPA deferred action on the requirements to address existing visibility impairment, discussions related to source impact (such as additional emission limitations, source retirement and replacement, construction activities, and enforceability of emission limitations) are not required in the SIPs at this time. However, Colorado has chosen to establish the mechanism for addressing existing visibility impairment and implementing BART once an existing source(s) has been identified as causing visibility impairment in a Class I area.

The Colorado Visibility SIP includes provisions which address Federal LTS requirements in "Long-term Strategy (LTS)" and in AQCC Regulation XV.F. (LTS). Additional information concerning the Federal LTS

requirements is contained in 52 FR 7802 (March 12, 1987).

Summary of Action

The December 21, 1987, submittal by the Governor of Colorado includes a visibility plan to meet the general plan requirements, monitoring strategy, and LTS of 40 CFR 51.302, 51.305, and 51.306 and the criteria discussed in 50 FR 28544 and 52 FR 45132. (See October 23, 1984 (49 FR 42670), and March 12, 1987 (52 FR 7802), for additional information.) The State commits to a review of the Visibility SIP every three years, making any changes deemed necessary. The SIP, therefore, has established the commitment to review the visibility requirements listed in 40 CFR Part 51 Subpart P—Protection of Visibility. The submittal will replace the Federal plans and regulations of 40 CFR 51.302, 51.305, and 51.306 in the Colorado SIP.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. This action will be effective 60 days from the date of the Federal Register notice unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted.

If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective October 11, 1988.

Final Action

EPA hereby approves the revisions to the Colorado Visibility SIP for general plan requirements, monitoring strategy, and LTS.

Note: EPA approved the NSR and Prevention of Significant Deterioration (PSD) for certain source categories. The Federal requirements will apply to those sources not covered under the approved Colorado NSR and PSD program. (See 46 FR 21180 (April 30, 1981) and 51 FR 31125 (September 2, 1986).)

EPA finds good cause exists for making the action taken in this notice immediately effective because the implementation plan revisions are already in effect under State law or regulation and EPA's approval poses no additional regulatory burden.

Under 5 U.S.C. 605(b), I certify that this SIP revision will not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the U.S. Court of Appeals for the appropriate circuit by October 11, 1988. This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

List of Subjects in 40 CFR Part 52

Air pollution control, Particulate matter, Incorporation by reference.

Note: Incorporation by reference of the State Implementation Plan for the State of Colorado was approved by the Director of the Federal Register on July 1, 1982.

Dated: July 25, 1988.

Lee M. Thomas,

Administrator.

Part 52 Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

Subpart G—Colorado

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7642.

2. Section 52.320 is amended by adding paragraph (c)(41) to read as follows:

§ 52.320 Identification of Plan

* * * * *

(c) * * *

(41) A revision to the SIP was submitted by the Governor on December 21, 1987, for visibility general plan requirements, monitoring, and long-term strategies.

(i) Incorporation by reference:

(A) Letter dated December 21, 1987, from Governor Roy Romer submitting the Colorado Visibility SIP revision.

(B) The visibility SIP revision, Regulation No. 3, "Regulation requiring an air contaminant emission notice, Emission Permit Fees", section XV, adopted by the Colorado Air Quality Control Commission on November 19, 1987.

§ 52.344 [Amended]

3. Section 52.344(c) is removed.

[FR Doc. 88-17112 Filed 8-11-88; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Parts 152, 153, 156, 158, 162, and 163

[OPP-30071D; FRL-3427-8]

Pesticide Registration Procedures; Pesticide Data Requirements; Cross References and Technical Amendments; Effective Date

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rules; Effective date.

SUMMARY: This document announces the effective date of two final regulations issued by the Agency on May 4, 1988. As required by section 25(a)(4) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA submitted two final regulations to both Houses of Congress for review prior to their taking effect. The first rule revised pesticide registration procedures and data requirements and policies; the second final rule contained cross-reference revisions and technical amendments pertaining to the first rule. These final rules were published in the Federal Register of May 4, 1988 (53 FR 15952). The minimum 60-day period for Congressional review has ended.

EFFECTIVE DATE: The regulation is effective on August 12, 1988.

FOR FURTHER INFORMATION CONTACT: By mail:

Jean Frane, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washngton, DC 20460.

Office location and telephone number: Room 1114, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-0944).

SUPPLEMENTARY INFORMATION: EPA issued a final regulation revising its pesticide registration procedures and modifying the product chemistry data requirements for pesticides. The final rule reorganized and renumbered a variety of pesticide regulations and created a new part in which to locate labeling requirements (which were not revised). In addition, the revision updated and clarified Agency policies pertaining to registration and registered products. A second final rule, issued on the same date, revised cross-references and made technical amendments elsewhere in pesticide regulations.

However, as required by section 25(a)(4) of FIFRA, the final rules could not take effect until they had been submitted to Congress for a period of 60 days of continuous Congressional session, as defined by section 25(a)(4). Since it was not possible to predict an exact date on which the Congressional

review period would end, the preamble to each final rule stated that EPA would issue a separate **Federal Register** notice after the review period was over announcing the effective date of the regulation. The 60-day period of continuous Congressional session has ended.

Accordingly, the final regulations promulgated on May 4, 1988, are effective on August 12, 1988.

List of Subjects in 40 CFR Parts 152, 153, 156, 158, 162 and 163

Administrative practice and procedure, Data requirements, Environmental protection, Intergovernmental relations, Labeling, Pesticides and pests, Policy statements, Reporting and recordkeeping requirements.

Dated: August 4, 1988.

Victor J. Kimm,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 88-18251 Filed 8-11-88; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Family Support Administration

45 CFR Parts 206 and 233

Application, Determination of Eligibility and Furnishing Assistance—Public Assistance Programs; Coverage and Conditions of Eligibility in Financial Assistance Programs; Alien Legalization

AGENCY: Family Support Administration, HHS.

ACTION: Final rule.

SUMMARY: These final rules implement provisions of the Immigration Reform and Control Act of 1986, Pub. L. 99-603, as they relate to the eligibility determination requirements of aliens applying for assistance payments under the Aid to Families with Dependent Children (AFDC) program, under title IV-A of the Social Security Act (the Act); and the adult assistance programs for the aged, blind, and disabled under titles I, X, XIV, and XVI (AABD) in Guam, Puerto Rico, and the Virgin Islands.

EFFECTIVE DATE: August 12, 1988.

FOR FURTHER INFORMATION CONTACT: Ms. Diann Dawson, Director, Division of Policy, Office of Family Assistance, Family Support Administration, Room B-428, 2100 Second Street, SW., Washington, DC 20201, telephone (202) 245-3290.

SUPPLEMENTARY INFORMATION: On December 24, 1987, interim final rules were published in the **Federal Register** (52 FR 48687-48689).

Legalization

Pursuant to section 245A(h) of the Immigration and Nationality Act (INA), as added by section 201 of the Immigration Reform and Control Act of 1986 (IRCA), Pub. L. 99-603, alliens who have continuously resided in the United States illegally since before January 1, 1982, can apply to the Immigration and Naturalization Service (INS) for an adjustment of their immigration status to that of lawful temporary resident. After a period of eighteen months in a temporary resident status, an alien can apply for adjustment to permanent resident status.

If the alien does not appy for such adjustment by the end of the thirty-first month after the alien is granted temporary resident status, or if adjustment is denied, the alien's status as a lawful temporary resident terminates, and the alien returns to an unlawful status.

Section 245A(h) explicitly disqualifies any alien who was granted lawful temporary resident status from eligibility for assistance payment under the AFDC program for a period of 5 years from the effective date of the receipt of such status. This disqualification period is maintained even though the temporary status may be changed to that of permanent status within the 5 year period. Accordingly, 45 CFR 233.50 is revised to indicate that this new group of aliens is temporarily disqualified from AFDC eligibility.

However, temporary resident alien applicants for assistance in the adult categories under Titles I, X, XIV, and XVI (AABD) in Guam, Puerto Rico, and the Virgin Islands are not subject to the disqualification provisions of the statute. Cuban and Haitian entrants, as defined in paragraph (1) or (2)(A) of section 501(e) of Pub. L. 96-422, as in effect on April 1, 1983, whose status has been adjusted to that of lawful temporary resident are also not subject to the disqualification provision and, if otherwise eligible, are entitled to assistance.

IRCA section 320 adds new section 210 to the INA to provide for granting lawful temporary resident status and eventually permanent resident status to certain aliens who performed seasonal agricultural work in the United States during a specified period of time. Special agricultural alien workers granted the temporary resident status are also temporarily disqualified for the 5 year period from assistance under the AFDC program; however, they are entitled to assistance, if otherwise eligible, under the adult programs in Guam, Puerto Rico, and the Virgin Islands.

IRCA section 303 adds new section 210 A to the INA to provide for granting lawful temporary resident status to replenishment agricultural workers if the Secretaries of Labor and Agriculture establish a shortage of workers to perform seasonal agricultural services in the United States beginning with fiscal year 1990 and ending with fiscal year 1993. Replenishment agricultural workers granted temporary resident status are also temporarily disqualified for the 5 year period from assistance under the AFDC program, however, they are entitled to assistance, if otherwise eligible, under the adult programs in Guam, Puerto Rico, and the Virgin Islands.

In addition, IRCA section 121 amends section 1137 of the Social Security Act to provide that beginning October 1, 1988, as a condition of an individual's eligibility for assistance under the AFDC, territorial assistance, and Medicaid programs, a State must require an individual to declare in writing whether he is a citizen or national of the United States, and if not, whether he is in a satisfactory immigration status. An individual must produce documents to establish satisfactory immigration status and the State must verify the individual's status through an automated or other system made available by INS, unless the Secretary of HHS grants a waiver. Regulations implementing this section of IRCA wll be published separately. On March 10, 1988, the Department published final regulations implementing IRCA section 204, which appropriates funds for fiscal years 1988 through 1991, to reimburse the States for the costs of providing public assistance, public health assistance, and educational services to certain aliens whose status is adjusted under IRCA (53 FR 7832-7864).

Pursuant to section 245 A(h) of the Immigration and Nationality Act, a disqualified alien who is either a parent or a sibling of an otherwise eligible child, will be excluded from an assistance unit in the same way that ineligible aliens have been excluded prior to the enactment of Pub. L. 99-603. However, IRCA section 201(b) provides that the income of a disqualified parent is considered available to his or her

dependent child by using the stepparent deeming formula at section 402(a)(31) of the Social Security Act and Federal regulations at 45 CFR 233.20(a)(3)(xiv). Accordingly, § 233.20 is revised to reflect this provision for deeming from the disqualified alien to his or her eligible child. Also, IRCA section 201(b) provides that where a disqualified alien is the brother or sister of a dependent child, the needs of the alien shall not be considered in determining the need of the dependent child. Therefore, 45 CFR 206.10 is revised to reflect that the needs and income of disqualified alien siblings are not considered in determining need of an otherwise eligible dependent child.

Response to Public Comments

A 60-day comment period was provided in the December 24, 1987, interim final rule. We received a comment from one county agency. Response to this comment follows.

Treatment of Income of Disqualified Siblings or Parents

Coment: One county agency expressed concern regarding the provision of not considering the needs and income of disqualified alien siblings when determining the eligibility and payment of an otherwise eligible dependent child. The county agency was concerned that the provision would conflict with a State court order indicating that a parent's income must be used first to meet the needs of an "unaided" child before being used to meet the needs of an eligible child or children.

Response: We have reviewed the county agency's explanation of the State court order and, based on the general information provided, can find no conflict with the provision that precludes consideration of the needs and income of disqualified alien siblings when determining the eligibility and payment of an otherwise eligible dependent child. We further believe that the Federal regulations at 45 CFR 233.20(a)(3)(vi)(B) with its reference to the deeming formula at 45 CFR 233.20(a)(3)(xiv) are applicable to the issues raised by the county agency. This deeming formula permits the disregard of an amount for the support of other individuals who are living in the home but whose needs are not taken into account in making the AFDC eligibility determination.

Regulatory Procedures

Executive Order 12291

Executive Order 12291 requires that a regulatory impact analysis be performed for any "major" rule. A "major" rule is defined as any rule that would result in annual effect on the national economy of $100 million or more; result in a major increase in costs or prices; or have significant adverse impacts on competition, employment, or productivity. The Department concludes that implementing the IRCA alien eligibility determination requirements does not constitute a major rule within the meaning of E.O. 12291 because it does not have an effect on the economy of $100 million or more or otherwise meet the threshold criteria. The effect of the final rule is to promulgate the statutory provisions and other conforming procedures to effectively implement the requirements of the law. Any impacts on the economy are due to the IRCA statutory requirements and not a result of these final rules. Accordingly, a regulatory impact analysis is not required.

Paperwork Reduction Act

Pursuant to the provisions of the Paperwork Reduction Act of 1980, Pub. L. 96-511, the Department has determined that this rulemaking will not impose any new recordkeeping, information collection, or reporting requirement requiring OMB approval.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires that a regulatory flexibility analysis be performed for each rule with a significant economic impact on a substantial number of small entities. Small entities are defined by the Act to include small businesses, small nonprofit organizations, and small government entities. The principal impact of these regulations is on States, which are not "small entities" within the meaning of the Act. We certify that this regulation will not, if promulgated, have a significant impact on a substantial number of small entities because it affects only the transfer of funds between the Federal Government and the States. Therefore, a regulatory flexibility analysis is not required.

(Catalog of Federal Domestic Assistance Program No. 13.780 Assistance Payments Maintenance Assistance)

List of Subjects

45 CFR Part 206

Grant programs—social programs, Public assistance programs.

45 CFR Part 233

Aliens, Grant programs—Social programs, Public assistance programs, Reporting and recordkeeping requirements.

Date: April 8, 1988.

Wayne A. Stanton,

Administrator, Family Support Administration.

Date: May 20, 1988.

Otis R. Bowen,

Secretary, Health and Human Services.

PART 233—COVERAGE AND CONDITIONS OF ELIGIBILITY IN FINANCIAL ASSISTANCE PROGRAMS

* * * * *

The interim rule published in the Federal Register of December 24, 1987 on pages 53 FR 48627-48629 is adopted as final with the following changes:

1. The authority citation for Part 233 continues to read as follows:

Authority: Secs. 1, 402, 406, 407, 1002, 1102, 1402, and 1602 of the Social Security Act (42 U.S.C. 301, 602, 606, 607, 1202, 1302, 1352, and 1382 note), and sec. 6 of Pub. L. 94-114, 89 Stat. 579 and Part XXIII of Pub. L. 97-35, 95 Stat. 843, Pub. L. 97-248, 96 Stat. 324, and Pub. L. 99-603.

2. Section 233.50 is amended by revising paragraph (b)(4) to read as follows:

§ 233.50 Citizenship and alienage.

* * * * *

(b) * * *

(4) Section 212(d)(5)—Aliens Granted Temporary Parole Status by the Attorney General, or

* * * * *

[FR Doc. 88-17669 Filed 8-11-88; 8:45 am]

BILLING CODE 4150-04-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 2-12; Notice 5]

Seating Systems; Correction

AGENCY: National Highway Traffic Safety Administration (NHTSA); DOT.

ACTION: Technical correction.

SUMMARY: This document corrects a typographical error in 49 CFR 571.207, *Seating systems.* This Federal Motor Vehicle Safety Standard (FMVSS) concerns the general performance requirements for seating systems in passenger cars, multipurpose passenger vehicles, trucks, and buses.

DATE: This correction is effective August 12, 1988.

FOR FURTHER INFORMATION CONTACT: Marvin L. Shaw, Office of Chief Counsel, National Highway Traffic

Safety Administration, 400 Seventh Street SW., Washington DC 20590 (202-366-2992).

SUPPLEMENTARY INFORMATION: It has come to the agency's attention that Section S4.2(a) of Standard No. 207, *Seating systems*, Title 49 of the Code of Federal Regulations (CFR) Part 571, contains a typographical error. This standard establishes requirements for seats, their attachment assemblies, and their installation to minimize the possibility of their failure by forces acting on them as a result of vehicle impact.

Section S4.2(a) should state that "In any position to which it can be adjusted—20 times the weight *of* the seat applied in a forward longitudinal direction." (See 35 FR 15290 at 15291; October 1, 1970.) (Emphasis added.) However, as published in the Code of Federal Regulations, most recently on October 1, 1987 (49 CFR 571.207), S4.2(a) states "In any position to which it can be adjusted—20 times the weight *on* the seat applied in a forward longitudinal direction." (Emphasis added.) This notice corrects that error.

This technical correction to Part 571 imposes no new duties or obligations on any party, nor alters any existing ones. Making this amendment simply ensures that the public will have a correct copy of the requirements in Part 571. For the preceding reasons, NHTSA finds that notice and comment on this correction notice are unnecessary, and that there is good cause for making the amendments effective in less than 30 days.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

Therefore, 49 CFR 571.207 is amended as follows:

PART 571—[AMENDED]

1. The authority citation for Part 571 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

§ 571.207 Standard No. 207; Seating Systems. [Amended]

2. Section S4.2(a) is revised to read as follows:

S4.2 *General performance requirements.*

* * * * *

(a) In any position to which it can be adjusted—20 times the weight of the seat applied in a forward longitudinal direction;

* * * * *

Issued on August 9, 1988.

Diane K. Steed,

Administrator.

[FR Doc. 88-18305 Filed 8-11-88; 8:45 am]

BILLING CODE 4910-59-M

National Highway Traffic Safety Admistration

49 CFR Part 585

[Docket No. 74-14; Notice 59]

Automatic Restraint Phase-In Reporting Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Technical amendment.

SUMMARY: NHTSA inadvertently omitted a relevant statutory section from the authority citation for the automatic restraint phase-in reporting regulation. This notice corrects that error.

DATE: The amendment made by this notice takes effect September 12 1988.

FOR FURTHER INFORMATION CONTACT: Stephen R. Kratzke, Office of Chief Counsel, NHTSA, 400 Seventh Street SW., Washington, DC 20590 (202-366-2992).

SUPPLEMENTARY INFORMATION: On March 1, 1986, NHTSA published a final rule establishing a new 49 CFR Part 585, *Automatic Restraint Phase-In Reporting Requirements* (51 FR 9800). In that rule, the agency listed the authority for Part 585 as 15 U.S.C. 1392 and 1407, with the delegation of authority at 49 CFR 1.50.

This authority citation inadvertently omitted the principal statutory source of NHTSA's authority to impose recordkeeping requirements on manufacturers and other persons subject to the National Traffic and Motor Vehicle Safety Act (the Safety Act). That statutory section is 15 U.S.C. 1401, subsection (b) of which specifies that:

> Every manufacturer of motor vehicles * * * shall establish and maintain such records and every manufacturer * * * shall make such reports, as the Secretary may reasonably require to enable him to determine whether such manufacturer * * * has acted or is acting in compliance with this title or any rules, regulations, or orders issued thereunder * * *

This notice amends the authority citation for Part 585 by adding 15 U.S.C. 1401 to the statutory sections listed in the authority citation. This amendment merely clarifies the source of NHTSA's authority to establish the reporting and recordkeeping requirements in Part 585. This amendment does not alter any manufacturer's existing responsibilities under Part 585, nor does it impose reporting and recordkeeping requirements on manufacturers not currently subject to Part 585. Accordingly, NHTSA finds for good cause that notice and opportunity for comment on this amendment are unnecessary.

List of Subjects in 49 CFR Part 585

Reporting and recordkeeping requirements.

In consideration of the foregoing the authority citation for 49 CFR Part 585 is revised as follows:

PART 585—[AMENDED]

Authority: 15 U.S.C. 1392, 1401, 1407; delegation of authority at 49 CFR 1.50.

Issued on August 9, 1988.

Diane K. Steed,

Administrator.

[FR Doc. 88-18304 Filed 8-11-88; 8:45 am]

BILLING CODE 4910-59-M

Proposed Rules

Federal Register
Vol. 53, No. 156
Friday, August 12, 1988

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.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 1

Administrative Regulations; Privacy Act Regulations

AGENCY: Office of the Secretary, USDA.

ACTION: Proposed rule.

SUMMARY: Notice is hereby given that the Department of Agriculture (USDA) proposes to amend 7 CFR 1.123 by adding one system of records to those exempted from certain sections of the Privacy Act of 1974 (5 U.S.C. 552a) pursuant to 5 U.S.C. 552a(k).

DATE: Comments must be received on or before September 12, 1988.

ADDRESS: Interested persons may submit written comments to: Kenneth E. Cohen, Assistant General Counsel, Research and Operations Division, Office of the General Counsel, United States Department of Agriculture, Washington, DC 20250, (202) 447-5565.

FOR FURTHER INFORMATION CONTACT: Barbara S. Good, Office of the General Counsel, USDA, (202) 447-3564.

SUPPLEMENTARY INFORMATION: These amendments are necessary to provide for exemption of a new Privacy Act system of records entitled "FCIC Compliance Division Review Cases, USDA/FCIC-2." A separate notice regarding USDA/FCIC-2 will be published in the **Federal Register**. This system will contain detailed information pertaining to cases in which the Federal Crop Insurance Corporation (FCIC) Compliance Division is involved. The information is collected during the course of reviews and investigations conducted by the Compliance Division and includes investigative notes, signed statements, affirmations and affidavits, correspondence, case history and status, contractual information, financial data and other related information, and reported findings by the Compliance Division and other entities such as the Office of Inspector General, USDA.

The authority for maintenance of this system is found at 7 U.S.C. 1501-1520. That legislation authorizes FCIC to be responsible for compliance activities pertaining to the provision of crop insurance coverage and the adjustment and payment of claims thereon.

This rule has been reviewed under Secretary's Memorandum 1512-1 and Executive Order No. 12291 and has been determined not to be a "major rule" since it will not have an annual effect on the economy of $100 million or more.

In addition, it has been determined that these rules will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 7 CFR Part 1

Privacy Act.

For the reasons set out in the preamble, it is proposed to amend 7 CFR, Subtitle A, Part 1, Subpart G, as follows:

PART 1—ADMINISTRATIVE REGULATIONS

1. The authority citation for Subpart G continues to read as follows:

Authority: 5 U.S.C. 552a.

2. Section 1.123 is amended by adding an entry for Federal Crop Insurance Corporation alphabetically to read as follows:

§ 1.123 Specific exemptions.

* * * * *

Federal Crop Insurance Corporation

FCIC Compliance Division Review Cases, USDA/FCIC-2

* * * * *

Done this 5th day of August 1988, at Washington, DC.

Richard E. Lyng,

Secretary of Agriculture.

[FR Doc. 88-18173 Filed 8-11-88; 8:45 am]

BILLING CODE 3410-14-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 87-ASW-30]

Airworthiness Directives; Sikorsky Model S-76A/B Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This notice proposes to amend an existing airworthiness directive (AD) which requires removal of electrical door locking actuators to prevent passenger door locks from jamming in the locked position on Sikorsky Model S-76A/B helicopters. This proposed AD would allow those helicopters which have installed an electric door lock manual override retrofit kit to be exempt from further compliance with the AD.

DATE: Comments must be recieved on or before September 12, 1988.

ADDRESSES: Comments on the proposal may be mailed in duplicate to: Rules Docket, Office of the Regional Counsel, FAA, Southwest Region, Fort Worth, Texas 76193-0007, or delivered in duplicate to: Office of the Regional Counsel, FAA Southwest Region, Room 158, Building 3B, 4400 Blue Mound Road, Forth Worth, Texas. Comments must be marked: Docket No. 87-ASW-30. Comments may be inspected at Room 158, Building 3B, Office of the Regional Counsel, Southwest Region, between the hours of 8 a.m. and 4 p.m. weekdays, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Terry Fahr, ANE-153, FAA, New England Region, Boston Aircraft Certification Office, 12 New England Executive Park, Burlington, Massachusetts 01803, telephone number (617) 273-7103.

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

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before or after the closing date for comments,

in the Rules Docket, Office of the Regional Counsel, 4400 Blue Mound Road, Fort Worth, Texas, for examination by interested persons. A report summarizing each FAA-public contact, concerned with the substance of the proposed AD, will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 87-ASW-30." The postcard will be date/time stamped and returned to the commenter.

This notice proposes to amend Amendment 39-5754 (52 FR 43054; November 9, 1987), AD 87-23-07, which currently required removal of Part Number (P/N) 22020256 electrical door locking actuators to prevent the passenger door locks from jamming in the locking position on Sikorsky Model S-76A/B helicopters. After issuing Amendment 39-5754, the FAA has determined that Sikorsky has designed a manual override kit, P/N 76070-20097, which allows the door lock to be manually overridden if an electrical door lock jams in the locked position. Therefore, the FAA is proposing to amend Amendment 39-5754 to exempt those helicopters which have installed a manual override kit, P/N 76070-20097, from compliance with the AD.

The regulations set forth in this notice would be promulgated pursuant to authority in the Federal Aviation Act of 1958, as amended (49 U.S.C. 1301, *et seq.*), which statute is construed to preempt state law regulating the same subject. Thus, in accordance with Executive Order 12612, it is determined that such regulations do not have federalism implications warranting the preparation of a Federalism Assessment.

This proposed amendment is relieving in nature and imposes no additional burden on any person. Therefore, I certify that this proposed amendment (1) is not a major rule under the provisions of Executive Order 12291; (2) is not a significant rule under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation has been prepared for this action and has been placed in the public docket. A copy of it may be obtained by contacting the Regional Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the FAA proposes to amend § 39.13 of Part 39 of the FAR as follows:

PART 39—[AMENDED]

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By amending Amendment 39-5754 (52 FR 43054; November 9, 1987), AD 87-23-07, by revising the applicability paragraph to read as follows:

Sikorsky Aircraft Division: Applies to all Sikorsky Model S-76A/B helicopters, certificated in all categories, equipped with electrical door locking actuators installed in accordance with Sikorsky Drawing 76088-20016 using actuator P/N 22020256 in left and right passenger doors, except those helicopters which have installed a manual override kit, P/N 76070-20097. (Docket 87-ASW-30)

* * * * *

Issued in Washington, DC, on August 3, 1988.

M.C. Beard,

Director, Office of Airworthiness.

[FR Doc. 88-18270 Filed 8-11-88; 8:45 am]

BILLING CODE 4910-13-M

FEDERAL TRADE COMMISSION

16 CFR Part 13

[File No. 881 0078]

West Point-Pepperell, Inc., et al.; Proposed Consent Agreement With Analysis To Air 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 allow, among other things, West Point-Pepperell to acquire J.P. Stevens & Co., Inc. through Magnolia Partners, L.P. The consent agreement would require respondents to divest certain towel and sheet-making assets and may require West Point-Pepperell to add certain additional assets to the divestitures package. The Commission has also entered into an "Agreement to Hold Separate" [1] with respondents. This Agreement to Hold Separate would become a part of the consent order.

DATE: Comments must be received on or before October 11, 1988.

ADDRESS: Comments should be directed to: FTC/Office of the Secretary, Room 136, 6th Street and Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Ernest Nagata, FTC/S-2105, Washington, DC 20580. (202) 326-2714.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, 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

Sheets, Towels, Trade practices.

Agreement Containing Consent Order to Divest

The Federal Trade Commission ("the Commission") having initiated an investigation into the proposed acquisition of the voting securities of J.P. Stevens & Co., Inc. ("J.P. Stevens") by Magnolia Partners, L.P. ("Magnolia"), a limited partnership in with STN Holdings, Inc., a subsidiary of West Point-Pepperell, Inc. ("West Point") is a general partner, and Bibb Sub, Inc. ("Bibb Su"), a company controlled by the NTC Group, Inc. ("NTC"), is a limited partner, and it now appearing that Magnolia, West Point and NTC are willing to enter into an agreement containing an Order to divest certain assets;

It is hereby agreed by and between West Point, by its duly authorized officer, NTC, by its duly authorized attorney, Magnolia, by its duly authorized partner, and counsel for the Commission that:

1. J.P. Stevens is a corporation organized under the laws of the State of Delaware with its office and principal

[1] Copies of the Agreement to Hold Separate and its amendments are available from the Commission's Public Reference Branch, H-130, 6th and Pennsylvania Avenue NW., Washington, DC 20580.

place of business located at Stevens Tower, 1185 Avenue of the Americas, New York, New York 10036.

2. Proposed respondent Magnolia is a limited partnership in which STN Holdings, Inc., a Delaware corporation and a subsidiary of West Point, is a general partner, and Bibb Sub, a Delaware corporation controlled by NTC, is a limited partner. Magnolia is organized under the laws of Delaware and its has its principal place of business located at 400 W. 10th Street, West Point, Georgia 31833.

3. Proposed respondent West Point is a corporation organized under the laws of the State of Georgia with its office and principal place of business located at 400 W. 10th Street, P.O. Box 71, West Point, Georgia 31833.

4. Proposed respondent NTC is a corporation organized under the laws of the State of Delaware with its office and principal place of business located at 111 West 40th Street, New York, New York 10018. NTC owns all of the stock of The Bibb Company, which owns all of the stock of Bibb Sub.

5. Proposed respondents admit all jurisdictional facts set forth in the draft to complaint here attached.

6. Proposed respondents waive:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

c. All rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this agreement; and

d. All rights under the Equal Access to Justice Act.

7. This agreement shall not become 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 draft of complaint contemplated thereby, 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 proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

8. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft of complaint here attached.

9. 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 Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following Order to divest in disposition of the proceeding and (2) make information public in respect thereto. When so entered, the Order shall have the same force and effect 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 complaint and decision containing the agreed-to Order to proposed respondents at their addresses as stated in this agreement shall constitute service. Proposed respondents waive any right they may 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 the agreement may be sed to vary or contradict the terms of the Order.

10. Magnolia has read the proposed complaint and the Order contemplated hereby. It understands that once the Order becomes final, it will be required to file one or more compliance reports showing that it has fully complied with the Order.

Magnolia further understands that it may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

11. West Point has read the proposed complaint and the Order contemplated hereby. It understands that once the Order becomes final, it will be required to file one or more compliance reports showing that it has fully complied with the Order.

West Point further understands that it may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

12. NTC has read the proposed compliant and the Order contemplated hereby. It understands that once the Order becomes final, it will be required to file one or more compliance reports showing that it has fully complied with the Order.

NTC further understands that it may be liable for civil penalties in the amount provided by the law for each violation of the Order after it becomes final.

Order

I

For purposes of this Order, the following definitions shall apply:

(A) "West Point" means West Point-Pepperell, Inc., its predecessors, subsidiaries, divisions, groups and affiliates controlled by West Point, and their respective directors, officers, employees, agents and representatives, and their successors and assigns.

(B) "J.P. Stevens" means J.P. Stevens & Co. Inc., its predecessors, subsidiaries, divisions, groups and affiliates controlled by J.P. Stevens, and their respective directors, officers, employees, agents and representatives, and their successors and assigns.

(C) "NTC" means The NTC Group, Inc., its predecessors, subsidiaries, divisions, groups and affiliates controlled by NTC, and their respective directors, officers, employees, agents and representatives, and their successors and assigns.

(D) "Magnolia" means Magnolia Partners, L.P., a limited partnership in which STN Holdings, Inc., a subsidiary of West Point, is a general partner, and Bibb Sub, a company controlled by NTC, is a limited partner Magnolia is organized under the laws of Delaware and it has its principal place of business located at 400 W. 10th Street, West Point, Georgia 31833.

(E) "Bibb Sub" means Bibb Sub, Inc., its predecessors, subsidiaries, divisions, groups and affiliates controlled by Bibb Sub, their respective directors, officers, employees, agents and representatives, and their successors and assigns.

(F) "Sheet and Towel Assets" means:

(1)(a) the Roanoke Plants Nos. 1 and 2, Patterson Plant Rosemary Plant and Delta Finishing Plant No. 4, all of which are towel manufacturing facilities located in Roanoke Rapids, North Carolina (the "Roanoke Facilities"); Whitehorse Plants Nos. 1 and 2, which are sheet manufacturing facilities located in Greenville, South Carolina; Brookneal Finishing and Cut and Sew Plant, which is a sheet finishing plant located in Brookneal, Virginia; and (b) the assets described in paragraph (2) of this definition F.

(2) All of J.P. Stevens' assets, properties, business and goodwill, tangible and intangible, (i) located at the facilities described in paragraph (1) of this definition F, (ii) primarily utilized (*i.e.*, more than 50% as determined in good faith by West Point and NTC) in the manufacture and sale of sheets and

towels are intended to be included within the scope of the Sheet and Towel Assets, whether or not reflected on the balance sheet accounts of J.P. Stevens, including, without limitation, the following:

(a) All machinery, fixtures, equipment, vehicles, furniture, tools and all other tangible personal property;

(b) All customer lists, vendor lists, catalogs, sales promotion literature, advertising materials, research material, technical information, management information systems, software, inventions, trade secrets, technology, know-how, specifications, designs, drawings, processes and quality control data;

(c) Inventory;

(d) Accounts and notes receivable;

(e) Intellectual property rights, trademarks and trade names, other than trademarks and trade names including the "J.P. Stevens" name;

(f) All right, title and interest in and to owned or leased real property together with appurtenances, licenses and permits;

(g) All right, title and interest in and to the contracts entered into in the ordinary course of business with customers (together with associated bid and performance bonds), suppliers, sales representatives, distributors, agents, personal property lessors, personal property lessees, licensors, licensees, cosignors and consignees;

(h) All rights under warranties and guarantees, express or implied;

(i) All books, records and files;

(j) All items of prepaid expense; and

(k) All known and unknown, liquidated or unliquidated, contingent or fixed, rights or causes of action which J.P. Stevens has or may have against any third party and all such rights which J.P. Stevens has or may have in or to any asset or property relating primarily to the Sheet and Towel Assets, excluding, however, all known or unknown, liquidated or unliquidated, contingent or fixed, causes of action which J.P. Stevens has or may have to the extent they arise out of or are related to any liability, obligation or claim not to be assumed by NTC.

With respect to a class of similar assets (such as trucks) a fraction of the use of which has been devoted to the Sheet and Towel Assets, such fraction of such class (or as close an approximation to such fraction as can be separately transferred) shall be included within the Sheet and Towel Assets.

(G) "Eligible Person" means (1) any person or persons approved in advance by the Commission or (2) Bibb Sub or another subsidiary of NTC, *provided*, however, that Bibb Sub or such other NTC subsidiary acquires the Sheet and Towel Assets pursuant to the agreement between West Point and NTC dated March 24, 1988, as amended and restated on March 31, 1988 or any amendment thereof that has the prior approval of the Commission, *Provided* further that such prior Commission approval shall not be required unless the amendment provides for (1) the sale of less than all the Sheet and Towel Assets, (2) any additional conditions of Closing, (3) any additional financing arrangements between West Point and NTC, or (4) deletion or modification of any covenant in paragraph 11 of such agreement.

(H) "Commission" means the Federal Trade Commission.

II

It is ordered that:

(A) If respondents, individually or collectively, acquire a majority (more than 50%) of the outstanding voting shares of J.P. Stevens, respondents West Point and Magnolia shall, within nine (9) months from the date this Order becomes final, divest, absolutely and in good faith, the Sheet and Towel Assets to an Eligible Person. The Agreement to Hold Separate shall continue in effect until such time as the Sheet and Towel Assets, and any additional assets ordered to be divested pursuant to Part VII of this Order ("Part VII Assets"), have been divested, and respondents West Point and Magnolia shall comply with all terms of said agreement. The purpose of the divestiture of the Sheet and Towel Assets and the Part VII Assets is to ensure their continuation as ongoing, viable assets and enterprises engaged in the same business in which they are presently employed and to remedy the lessening of competition alleged in the Commission's complaint.

(B) If respondents collectively acquire less than a majority (50% or less) of the outstanding voting shares of J.P. Stevens, respondents shall divest on the New York Stock Exchange absolutely and in good faith all their interest in such shares within six (6) months from the date this Order becomes final. Pending such divestiture, respondents shall not, directly or indirectly, (i) exercise dominion or control over, or otherwise seek to influence, the management, direction, or supervision of the business of J.P. Stevens, (ii) seek or obtain representation on the Board of Directors of J.P. Stevens, (iii) exercise any voting rights attached to the shares, (iv) seek or obtain access to any confidential or proprietary information of J.P. Stevens, or (v) take any action or omit to take any action in a manner that would be incompatible with the status of West Point as a passive investor in J.P. Stevens.

III

It is further ordered that, pending divestiture, respondents West Point and Magnolia shall not make or permit any deterioration in the value of the Sheet and Towel Assets or any other assets ordered to be divested pursuant to Part VII herein which may impair their present capacity or marketability

IV

It is further ordered that, the Sheet and Towel Assets shall not be divested, directly or indirectly, to anyone who is at the time of the divestiture an officer, director, employee or agent of, or under the control, direction or influence of West Point or anyone who is not an Eligible Person.

V

It is further ordered that:

(A) If respondents West Point and Magnolia have not divested the Sheet and Towel Assets within the nine month period, respondents shall consent to the appointment by the Commission of a trustee to divest the Sheet and Towel Assets. In the event that the Commission brings an action pursuant to section 5(a)(1) of the Federal Trade Commission Act, 15 U.S.C. 45(a)(1), or any other statute enforced by the Commission, respondents shall consent to the appointment of a trustee in such action. The appointment of a trustee shall not preclude the Commission from seeking civil penalties and other relief available to it for any failure by West Point to comply with Parts II through XII of this Order.

(B) If a trustee is appointed by a court or the Commission pursuant Part V(A) of this Order, respondents shall consent to the following terms and conditions regarding the trustee's duties and responsibilities:

(1) The Commission shall select the trustee, subject to the consent of West Point, which shall not be unreasonably withheld. The trustee shall be a person with experience and expertise in acquisitions and divestitures.

(2) The trustee shall have the power and authority to divest the Sheet and Towel Assets that have not been divested by respondents West Point and Magnolia within the time period for divestiture in Part II. The trustee shall have nine (9) months from the date of

appointment to accomplish the divestiture, which shall be subject to the prior approval of the Commission and, if the trustee is appointed by a court, subject also to the prior approval of the court. If, however, at the end of the nine-month period the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission or by the court for a court-appointed trustee; *Provided*, however, that the Commission, or the court for a court-appointed trustee, may only extend the divestiture period two (2) times.

(3) The trustee shall have full and complete access to the personnel, books, records and facilities of Magnolia, West Point, J.P. Stevens, and the Sheet and Towel Assets. Respondents West Point and Magnolia shall develop such financial or other information as such trustee may reasonably request and shall cooperate with the trustee. Respondents shall take no action to interfere with or impede the trustee's accomplishment of the divestiture.

(4) The power and authority of the trustee to divest shall be at the most favorable price and terms available, but at no minimum price, consistent with the Order's absolute and unconditional obligation to divest and the purposes of the divestiture as stated in Part II.

(5) The trustee shall serve at the cost and expense of respondents West Point and Magnolia on such reasonable and customary terms and conditions as the Commission or a court may set, including the employment of accountants, attorneys or other persons reasonably necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the sale and all expenses incurred. After approval by the Commission or the court of the account of the trustee, including fees for his or her services, all remaining monies shall be paid to Magnolia and the trustee's power shall be terminated. The trustee's compensation shall based passed at least in significant part on a commission arrangement contingent on the trustee's divesting the Sheet and Towel Assets.

(6) Within sixty (60) days after appointment of the trustee and subject to the approval of the Commission and, if the trustee was appointed by a court, subject also to the prior approval of the court, respondents West Point and Magnolia shall execute a trust agreement that transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestiture.

(7) If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed.

(8) The trustee shall report in writing to respondents and the Commission every sixty (60) days concerning the trustee's efforts to accomplish divestiture.

VI

It is further ordered that, in the event that the Magnolia partnership agreement requires NTC to consent to any action in order to enable West Point to comply with its obligations under this Order, NTC shall consent to such action.

VII

It is further ordered that, within ninety (90) days after this Order becomes final, the Commission may order West Point, pursuant to the terms of this Order:

(A) (1) To divest such additional assets, as the Commission determines will ensure the divestiture of the Sheet and Towel Assets as ongoing, viable enterprises, engaged in the businesses in which these Sheet and Towel Assets are presently employed. Such additional J.P. Stevens assets may include textile machinery, finishing equipment, cutting and sewing equipment and product names, designer names, trademarks and licenses therefor; and

(2) To sell yarn needed to balance the production from the Sheet and Towel Assets; to provide on a commission basis finishing and cut and sew services to the extent that the Commission determines the facilities included in the Sheet and Towel Assets are insufficient for that purpose; and to continue the availability of J.P. Stevens' computer programs. All such sales shall be made and all such services shall be provided for such term, not to exceed one (1) year after this divestiture is complete, as the Commission may see fit; *Provided* that if NTC or its subsidiary has purchased the Sheet and Towel Assets, no divestiture of additional assets or provision of services pursuant to Parts VII (A)(1) or VII (A)(2) will be required without the agreement of NTC.

(B) (1) To divest the J.P. Stevens Hanna-Pickett sheeting mill in the Rockingham, North Carolina, and, if the Commission determines it necessary to make the Hanna-Pickett sheeting mill a viable and salable economic unit, the J.P. Stevens Abbeville yarn plant in Abbeville, South Carolina; and

(2) To divest any one (1), two (2) or three (3) of the following trademarks and designer licenses:

(i) Carlin trademark,

(ii) The Ralph Lauren license,

(iii) The Gloria Vanderbilt license,

(iv) The Eillene West license,

(v) The Perry Ellis license, and

(vi) The Collier-Campbell license,

Provided, however, that the commercial value of trademarks and licenses ordered to be divested pursuant to this Part VII (B) plus the commercial value or product names, designer names, trademarks and licenses therefor ordered to be divested under Part VII (A) shall not exceed the combined commercial value of the three most valuable trademarks and licenses listed in Part VII (B); for purposes of this provision, relative "commercial value" shall be based on the sales of sheet and towel products under each trademark, product name or designer license during the fiscal year preceding the date on which this Order becomes final.

Divestitures under Part VII shall be made within nine (9) months of the Commission's determination that such divestiture is necessary and shall be made only to an acquirer or acquirers, and only in the manner, that shall receive the prior approval of the Commission. The purpose of the divestiture of the Hanna-Pickett sheeting mill, and if so ordered, the Abbeville yarn plant, is to ensure the continuation of the Hanna-Pickett sheeting mill as an ongoing, viable enterprise engaged in the same business in which it is presently employed and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's complaint. The purpose of the divestiture of product names, designer names, trademarks and licenses therefor is to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's complaint.

If the Part VII (B) assets have not been divested within the nine-month period, respondents West Point and Magnolia shall consent to the appointment of a trustee pursuant to the provisions contained in Part V. The trustee shall have all of the powers and duties and shall act in all respects in accordance with the terms and conditions contained in Part V.

VIII

It is further ordered that any assets ordered to be divested pursuant to Part VII shall not be divested, directly or indirectly, to anyone who is at the time of the divestiture an officer, director, employee or agent of, or under the control, direction or influence of West Point or anyone who is not an Eligible Person.

IX

It is further ordered that, for a period of ten (10) years from the date this Order becomes final, West Point shall cease and desist from acquiring, without the prior approval of the Commission, directly or indirectly, through subsidiaries or otherwise, the whole or any part of the stock, share capital, assets, any interest in or any interest of, any concern, corporate or non-corporate, engaged in the United States in the business of manufacturing terry cloth, terry towels, sheets or pillowcases; *Provided,* however, that these prohibitions shall not relate (i) to the construction of new facilities, (ii) to the acquisition of assets outside of the United States, (iii) to the acquisition of any interest in, or the whole or part of the stock or share capital of, any company engaged in the manufacture, distribution or sale of sheets or towels outside of the United States if such company has annual sales in the United States of less than one percent of the then current respective total United States annual sales of sheets or towels, or (iv) to the acquisition of used assets that West Point intends to relocate to existing or new facilities for use in production of sheets and towels if such used assets have production capacity of less than one percent of the United States' then current respective capacity for the production of sheets or towels. Beginning one (1) year from the date this Order becomes final and annually thereafter for nine (9) more years, West Point shall file with the Commission verified written reports of its compliance with this part.

X

It is further ordered that, within sixty (60) days from the date this Order becomes final and every sixty (60) days thereafter until it has fully complied with Parts II and VII of this Order, respondents West Point and Magnolia shall file reports in writing to the Commission setting forth in detail the manner and form in which they intend to comply, are complying or have complied therewith.

All such reports shall include, in addition to such other information and documentation as may hereafter be requested, (a) a specification of the steps taken by such respondents to make public their desire to divest the Sheet and Towel Assets and the Part VII (B) Assets, (b) a list of all persons or organizations contacted about the Sheet and Towel Assets and the Part VII (B) assets, (c) a summary of all discussions and negotiations together with the identity and address of all interested persons or organizations, and (d) copies of all reports, internal memoranda, offers, counteroffers, communications and correspondence concerning such divestiture.

XI

It is further ordered that, for the purpose of determining or securing compliance with this Agreement, subject to any legally recognized privilege, and upon written request with reasonable notice to West Point made to its principal office, West Point shall permit any duly authorized representative or representatives of the Commission:

(9) Access during the office hours of West Point and J.P. Stevens, in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of West Point or J.P. Stevens relating to compliance with this Order;

(10) Upon five (5) days' notice to West Point and without restraint or interference from them, to interview officers or employees of West Point or J.P. Stevens, who may have counsel present, regarding any such matters.

Any information or documents furnished to or obtained by the Commission from West Point or J.P. Stevens shall be accorded such confidential treatment as is available pursuant to sections 6(f) and 21 of the Federal Trade Commission Act, as amended.

XII

It is further ordered that respondents West Point and Magnolia shall notify the Commission at least thirty (30) days prior to any proposed change in the organization such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change that may affect compliance obligations arising out of this Order.

Concurring Statement of Commissioner Strenio, in Which Commissioner Azcuenaga Joins, in West Point-Pepperell/J.P. Stevens

My preference in this matter was to seek a preliminary injunction (pending an administrative proceeding at the FTC) in order to secure stronger safeguards for consumers. However, lacking the support of a Commission majority for that approach, I have voted to accept tentatively the proposed consent.

This vote was cast in recognition of two facts. First, the proposed consent offers more relief than would be obtained in its absence. Second, the proposed consent appears to contain relief that is far from trivial.

I will examine closely any submissions received by the agency during the public comment period before deciding what, if any, further action to take.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has provisionally accepted an agreement containing a proposed consent order with Magnolia Partners, L.P. ("Magnolia"), West Point-Pepperell, Inc. ("West Point"), and The NTC Group, Inc. ("NTC"), collectively referred to as "respondents."

On July 29, 1988, the Commission entered into an agreement containing the proposed consent order with Magnolia, West Point, and NTC in settlement of a proposed complaint challenging the acquisition of the voting securities of J.P. Stevens, Inc. ("J.P. Stevens") by Magnolia. Magnolia is a limited partnership controlled by West Point, with a subsidiary of NTC as a limited partner. The proposed complaint states that the Commission has reason to believe that, in the absence of an adequate divestiture of certain J.P. Stevens assets to NTC, the acquisition of J.P. Stevens voting securities by Magnolia (the "Acquisition") would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act. The proposed complaint specifically alleges that the Acquisition may substantially lessen competition in the manufacture, distribution, and sale of towels, and in the manufacture, distribution, and sale of sheets.

To remedy the alleged anticompetitive results of the Acquisition, the agreement's proposed consent order would (among other things) require Magnolia to sell ("divest") certain of J.P. Stevens' towel-making and sheet-making assets, including: (a) J.P. Stevens' Roanoke Plants Nos. 1 and 2, Patterson Plant, Rosemary Plant and Delta Finishing Plant No. 4, all of which are towel-making facilities located in Roanoke Rapids, North Carolina; (b) J.P. Stevens' Whitehorse Plants Nos. 1 and 2, which are sheeting-manufacturing facilities located in Greenville, South Carolina; and (c) the Brookneal Finishing and Cut and Sew Plant located in Brookneal, Virginia. As described in greater detail below, the Commission may require West Point to add certain additional assets to the divestiture package.

The Commission has placed the proposed complaint and the provisionally accepted consent order on the public record for sixty (60) days so

that interested parties may comment on it. The Commission is particularly interested in the opinions of the public on the appropriateness of divesting the additonal assets described in Part VII of this agreement. Comments received during this period will become part of the public record, unless commenters request confidential treatment. Commenters desiring confidential treatment must do so by printing "Confidential Treatment Requested" across the top of the first page of their comments. After the end of the sixty day comment period, the Commission will review the proposed complaint and consent order and the comments received thereon, and will decide whether it should withdraw from the consent agreement or make final the agreement's proposed consent order.

If the Commission withdraws from the agreement, it may: (1) Determine that no relief is required; (2) attempt to negotiate with respondents and make necessary modifications in the proposed consent order; or (3) initiate litigation to compel West Point to divest certain assets or seek any other relief consistent with section 7b of the Clayton Act or section 5 of the Federal Trade Commission Act.

In additon to provisional acceptance of the proposed consent order, the Commission has entered into an "Agreement to Hold Separate" with respondents. This agreement will maintain the separate identity and individual viability of J.P. Stevens during the public comment period. The proposed consent order expressly makes the Agreement to Hold Separate a part of the consent order.

If, at the end of the comment period, the Commission believes further enforcement action is warranted and withdraws from the proposed consent agreement, the Commission may seek any relief it deems appropriate, including a federal court order under section 13(b) of the Federal Trade Commission Act. In such a court action, the Commission may request (among other things) an extension of the "Hold Separate" provisions in order to prevent any commingling of J.P. Stevens' businesses or assets with West Point's until a final adjudication on the merits of any administrative action the Commission may initiate.

The purpose of this analysis is to facilitate public comment on the proposed consent order. It is not intended to constitute an official interpretation of the proposed complaint, consent order, or Agreement to Hold Separate, or to modify in any way their terms.

The Proposed Consent Order

Part I

The introductory paragraph of the proposed consent order defines the terms used in the order.[1] Subpart (f) describes the J.P. Stevens "Sheet and Towel Assets," and Subpart (G) defines an "Eligible Person" to which the Sheet and Towel Assets may be divested. The term "Eligible Person" includes NTC and its subsidiaries, so long as they acquire the Sheet and Towel Assets pursuant to a specified agreement betweeen West Point and NTC.

Part II

Part II of the proposed consent order provides that if respondents acquire a majority of J.P. Stevens' outstanding voting shares, they must, within nine months, fully divest the Sheet and Towel Assets to an Eligible Person. Should respondents not acquire a majority of Stevens' voting shares, Subpart (B) requires respondents to be passive investors in Stevens, and to divest themselves of all Stevens shares within six months from the date the order becomes final.

Part III

Part III of the proposed consent order prohibits West Point and Magnolia from causing or permitting deterioration of the value of the Sheet and Towel Assets or any other assets which may be ordered to be divested.

Parts IV, VIII

Parts IV and VIII of the proposed consent order prohibit the divestiture of the Sheet and Towel Assets, or other assets ordered to be divested pursuant to Part VII, to anyone under the control, direction, or influence of West Point or anyone who is not an Eligible Person.

Part V

Part V of the proposed consent order provides that, if the Sheet and Towel Assets have not been divested within nine months, respondents will consent to the appointment by the Commission of a trustee to divest the assets. The responsibilities of the trustee are also specified in detail.

Part VI

Part VI of the proposed consent order requires NTC to consent, whenever such consent is necessary, to any action enabling West Point to comply with its obligations under the Order.

[1] The proposed complaint also contains several definitions of terms.

Part VII

Part VII of the proposed consent order provides that, within 90 days after the Order becomes final, the Commission may order West Point to divest certain assets in addition to the Sheet and Towel Assets. Specifically, Subpart (A) of Part VII provides, in order to assure the viability of the Sheet and Towel Assets, that the Commission may require West Point to divest additional Stevens assets, including textile machinery, finishing equipment, cutting and sewing equipment and product names, designer names, trademarks and licenses therefor. In addition, West Point may be required to (a) sell yarn needed to balance production from the Sheet and Towel Assets; (b) provide finishing and cutting and sewing services on a commission basis; and (c) continue the availability of J.P. Stevens' computer programs for a period not to exceed one year. Pursuant to Subpart (B)(1), the Commission also may require the divestiture of J.P. Stevens' Hanna-Pickett sheeting mill in Rockingham, North Carolina, and its Abbeville yarn plant in Abbeville, South Carolina. Subpart (B)(2) provides that the Commission may also require West Point to divest up to three trademarks and designer licenses from those listed in that subpart.

Part IX

Paragraph IX of the proposed consent order would require, with certain exceptions, prior Commission approval for ten years of any acquisition by West Point of any interest (above a specified minimum threshold) in any business engaged in the United States in the manufacture of terry cloth, terry towels, sheets or pillowcases.

Part X

Paragraph X of the proposed consent order requires West Point and Magnolia to make compliance reports every sixty days until all divestitutes required by the Order and Commission are completed.

Part XI

Part XI of the proposed consent order would permit access by Commission representatives to records and documents of West Point and J.P. Stevens to assure compliance with the proposed order.

Part XII

Part XII would require West Point and Magnolia to give the Commission 30 days' notice of any change in their organization that may affect their compliance obligations under the order.

The Agreement to Hold Separate

The Agreement to Hold Separate, as amended, provides generally that West Point and Magnolia will hold separate those J.P. Stevens assets and businesses ordered to be divested (except such portion as is transferred to NTC or its subsidiary) for a period of 210 days following the purchase of J.P. Stevens' stock, or three business days after the Commission withdraws its acceptance of the consent agreement, whichever comes sooner.

Pursuant to the hold separate agreement, neither West Point nor Magnolia may exercise direction or control over, or influence directly or indirectly the operations of J.P. Stevens during the pendency of the consent order and the hold separate agreement, with nine specific exceptions listed in the hold separate agreement. Further, the hold separate agreement specifically permits West Point and Magnolia to divest all or parts of J.P. Stevens' aircraft maintenance, residential carpets, automotive carpets and fabrics, apparel fabrics, and industrial fabrics businesses, subject to applicable laws, including the Hart-Scott-Rodino Antitrust Improvements Act.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 88-18237 Filed 8-11-88; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HOUSING URBAN DEVELOPMENT

Office of the Assistant Secretary of Community Planning and Development

24 CFR Part 570

[Docket No. R-88-1374; FR-2381]

Urban Development Action Grant (UDAG); Applications from Consortia of Small Cities

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Proposed rule.

SUMMARY: The rule proposes to permit consortia of geographically proximate cities of less than 50,000 to apply for grants on behalf of a member city that is otherwise eligible for assistance but unable to handle independently the administrative or financial burden of a desired project.

DATES: *Comments Due:* October 11, 1988.

ADDRESSES: Interested persons are invited to submit comments to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Communications should refer to the above docket number and title. A copy of each communication will be available for public inspection during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Stanley Newman, Director, Office of Urban Development Action Grants, Room 7262, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410, (202) 755-6290. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Housing and Urban Rural Recovery Act of 1983, Pub. L. 98-181, amended section 119(i) of the Housing and Community Development Act of 1974, 42 U.S.C. 5318, to permit geographically proximate cities of less than 50,000 population to form consortia to apply for grants on behalf of a member city that is otherwise eligible for assistance. Under the revised statute, a consortia may include county governments that are not urban counties, and grants awarded to the consortia shall be administered in compliance with eligibility requirements applicable to individual cities.

This statutory change was made to address a concern that geographically proximate smaller communities may face common economic development problems which are beyond the administrative or financial capacity of any one of the communities to address independently. The revised statute allows such communities to apply jointly for UDAG assistance on behalf of an eligible distressed city and thereby provide the management framework necessary to carry out the project. The involved communities may include a non-urban county, or UDAG eligible or ineligible communities, but must include at least one eligible small city.

The proposed rule would implement the statutory change by setting forth departmental policies and procedures governing applications for, and the awarding of grants to, consortia of communities.

Findings

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR Part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of Rules Docket Clerk at the above address.

This rule does not constitute a "major rule" as that term is defined in section 1(b) of Executive Order 12291 issued by the President on February 17, 1981. Analysis of the proposed rule indicates that it does not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal State, or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Under the Regulatory Flexibility Act (5 U.S.C. 601), the Undersigned certifies that this rule would not have a significant economic impact on a substantial number of small entities because the number of applications expected would not be substantial. The funding for the UDAG program has been reduced in recent years, and only one-fourth of the funding is allocated to small cities. Applications submitted because of the consortia arrangement will have to compete with individual small cities applications and the Department does not anticipate that there will be very many for consideration.

In accordance with the Paperwork Reduction Act of 1980 (Pub. L 96-511), the reporting or recordkeeping provisions that are included in this regulation have been submitted to the Office of Management and Budget (OMB).

This rule is listed as item number 1026 in the Department's Semiannual Agenda of Regulations published October 26, 1987 (52 FR 40358) under Executive Order 12291 and the Regulatory Flexibility Act.

The Catalogue of Federal Domestic Assistance number is 14.221—Urban Development Action Grants.

List of Subjects in 24 CFR Part 570

Community development block grants, Grant programs: Housing and community development, Loan programs: Housing and community development, Low and moderate income housing, New communities, Pockets of poverty, Small cities.

Accordingly, the Department proposes to amend 24 CFR Part 570 as follows:

PART 570—[AMENDED]

1. The authority citation for Part 570 is revised to read as follows:

Authority: Title I, Housing and Community Development Act of 1974 (42 U.S.C. 5301–5320); sec. 7(d), Department of HUD Act, (42 U.S.C. 3535(d)).

2. A new § 570.467 is added to read as follows:

§ 570.467 Specific provisions for consortia of small cities applying for UDAG funds.

(a) *General.* Beginning with the July, 1988 funding round (represented in the table in § 570.460(a) as the May 1–31 application period, the June 1–July 31 review period, and the July 31 decision date), geographically proximate cities of less than 50,000 population may combine to apply for grants on behalf of a member city that is otherwise eligible for assistance under this subpart. Grants awarded to such consortia shall be administered in compliance with eligibility requirements applicable to individual cities, as set forth in this subpart. For purposes of this section, a consortium may include county governments that are not urban counties. To be eligible, the following general requirements must be met:

(1) Member communities of a consortium must be geographically proximate (i.e. located within normal commuting distance to the project) to the eligible distressed city or cities for which the application is being submitted, as determined by the appropriate HUD field office based on data and analysis supplied by the applicant.

(2) The project site must be located in an area which is within the jurisdiction of a member of the consortium;

(3) At least 51% of the jobs and taxes must go to an eligible distressed city or cities.

(4) All the jobs and taxes to be generated by the project will be counted in the calculation of project selection points.

(b) *Additional requirements.* In addition to the general requirements set forth in paragraph (a) of this section, the following requirements must be met:

(1) The application must include, in addition to the requirements of § 570.458, an executed cooperation agreement signed by all member communities and designating the member unit to government whose chief executive officer will be administratively responsible for the project and the responsible federal official for NEPA, historic preservation and other statutory and regulatory requirements, as set forth in § 570.458(c)(14). The cooperation agreement must also identify the expected project benefits, i.e., jobs, taxes and repayment and how these project benefits will be allocated among the member communities and the distressed city or cities.

(2) The application must include certification as to each member's authority to enter into the cooperation agreement.

(3) Each member of the consortium must meet all the Fair Housing and Equal Opportunity requirements set forth in this subpart.

(4) UDAG repayments either must go to the eligible city or eligible cities receiving project benefits or must be used entirely for the benefit of these eligible cities.

(c) *Other considerations.* If the benefits go to one eligible city, then the impaction and distress rankings of that city will be used. If more than one eligible distressed city is receiving benefits, the impaction and distress scores will be recalculated based on the combined characteristics of the communities receiving benefits.

Date: February 26, 1988.

Jack R. Stokvis,

General Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 88–18317 Filed 8–11–88; 8:45 am]

BILLING CODE 4210-29-M

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 1710

[Docket No. R-88-1390; FR-2503]

Amendments Relating to Interstate Land Sales Registration

AGENCY: Assistant Secretary for Housing—Federal Housing Commissioner Office of Lender Activity and Land Sales Registration, HUD.

ACTION: Proposed rule.

SUMMARY: The Department, under the authority provided by 15 U.S.C. 1702(c), is proposing to amend its regulations to provide a regulatory exemption from the registration requirements of the Interstate Land Sales Full Disclosure Act. The proposed exemption would apply to sales in subdivisions (as that term is defined by the Act) of 100 or more lots that are created by the continual acquisition and disposal of lots in geographically scattered locations which, unless extraordinary steps are taken, are offered under one common promotional plan and are, therefore, subject to registration. However, because of the very nature of these types of operations with a constantly revolving inventory of lots in scattered and diverse parts of the country, registration is impractical from both the registrant's and the registering agency's standpoint.

The proposed exemption will allow developers of these subdivisions to operate without the necessity of taking the steps necessary to avoid operating under one common promotional plan and maintaining a registration. Promulgation of this exemption will not decrease the consumer protections provided by the Act but, rather, will provide information formerly not made available to prospective purchasers by developers of these types of subdivisions.

DATE: *Comment Due Date:* October 11, 1988.

ADDRESS: Interested persons are invited to submit comments regarding this rule to the Rules Docket Clerk, Office of the General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Roger G. Henderson, Acting Director, Interstate Land Sales Registration Division, Department of Housing and Urban Development, Room 6278, Washington, DC 2410. Telephone (202) 755–0502. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: A segment of the land sales industry conducts its operations by continually acquiring and selling geographically dispersed multiple-lot sites. Individual sites contain fewer than 100 lots but are ineligible for the 100-lot exemption (24 CFR 1710.6) since, when two or more of the sites are offered under a single common promotional plan, the offering exceeds 100 lots and is subject to registration. Likewise, these multiple site offerings are ineligible for the scattered site exemption (24 CFR 1710.8) since, invariably, one or more of the sites will exceed the 20 lot-per-site limitation. Therefore, since these multiple site subdivisions are offered and sold under a single common promotional plan, all such multiple site offerings must either be registered or qualify for one of the available exemptions from registration. Typically, these sites are created from abandoned farms, undeveloped parcels in remote locations and similar vacant land. In an overwhelming majority of cases the

developers of these multiple site subdivisions offer no facilities or amenities but rather, sell the land on an "as is" basis.

To avoid the difficulties of a multiplicity of registrations and the near impossibility of a single registration, these developers must structure their offerings so that eligibility for the 24 CFR 1710.6 exemption is attainable. To accomplish this eligibility, the multiple sites are grouped so that the total number of lots is fewer than 100 and the corresponding promotion and sales activity is limited to that combination of multiple sites, totally isolated from any other site or any other multiple site combination(s) which the developer owns or acquires in the future. In other words, these developers must create and maintain separate subdivisions of fewer than 100 lots each and strictly adhere to the principles of separability; i.e., no common advertising, name, telephone number, address or sales force and, probably the most difficult of all, no cross-referrals. In order to maintain the necessary separability, the only acceptable element of commonality is ownership.

The proposed rule will provide relief from the registration requirements placed upon developers of these types of operations by creating the "Multiple Site Subdivision Exemption". This exemption will permit developers of these numerous sites to promote and sell the revolving inventory of lots under a single common promotional plan without registration by simply meeting certain eligibility requirements which are, for the most part, already characteristic of the offerings, and by providing general information about real estate ownership along with a minimum of information about specific lots.

Under the proposed exemption: The land being offered must be sold "as is" and must meet all local codes and standards; and amenities or facilities used in advertisements or other promotional materials must be completed and in the condition advertised; each lot must be accessible by a road; any exceptions to title must be approved by the purchaser in writing; the purchaser must be contractually provided a seven day cancellation period; a warranty deed (or its equivalent) must be delivered within 180 days of the date of sale; the purchaser, or spouse, must make an on-site inspection; payments must be escrowed until a deed is delivered; and purchasers must be provided a statement which includes warnings about the risks of buying land.

The proposed exemption would not be available to offerings where the developer acquires lots in a subdivision which was established by another developer for the purpose of making sales. This prohibition would exist whether the acquisition was, for example, from an active developer, residual inventory from a previous developer, through tax delinquency sales of from individual lot owners. It is felt that individual purchasers from these "secondary" developers need the intended benefits of disclosure and the protections of the Act, and the offering can be easily registered or qualify for one of the existing exemptions.

Likewise, the proposed exemption would not be applicable to any individual site of 100 or more lots nor to an individual site of fewer than 100 lots where the developer either owns adjacent land or has an option, or other evidence of intent, to acquire adjacent land which, when taken cumulatively, would or could equal 100 or more lots.

Therefore, a developer who is operating under the proposed exemption and acquires a separate site containing or potentially containing 100 or more lots as described in either of the two preceding paragraphs, would necessarily be required to isolate that site from any other eligible multiple site common promotional plan(s). The ineligible site would then have to be registered or qualify for one of the other available exemptions, but the principles of separability would have to be strictly applied.

In addition, subsequent to the effective date of the proposed exemption, OILSR will not recognize artificial barriers established for the sole purpose of segregating lot groupings to give the appearance of qualification for the 100 lot exemption described at 24 CFR 1710.6. To implement this policy, the Department is proposing a closer adherance to the Congressional intent by restricting eligibility for the 24 CFR 1710.6 exemption to the smaller, individual subdivision where the developer owns fewer than 100 lots and where the developer's plan of operation is not to continually acquire and dispose of multiple sites in geographically dispersed locations.

The proposed new exemption is a regulatory exemption and could be listed in 24 CFR 1710.14 but, because of the unique character of this exemption, it is being added as a new § 1710.15, Regulatory Exemption—Multiple Site Subdivision—Determination Required. The termination provisions of 24 CFR 1710.16 are included in the new section and the anti-fraud provisions of 24 CFR 1710.4 (b) and (c) would also apply to this exemption.

Also, a technical change is proposed to add the definition of the term "Site", which is currently included in the exemption guidelines, to the definitions in § 1710.1 of the Regulations.

A finding of No Significant Impact with respect to the environment has been made in accordance with HUD Regulations in 24 CFR Part 50 which implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410.

This rule does not constitute a "major rule" as that term is defined in section 1(b) of the Executive Order on Federal Regulation issued by the President on February 10, 1981. Analysis of the rule indicates that it does not: (1) Have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, state or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The rule was listed as item H-47-86 (Sequence Number 924) in the Department's Semiannual Agenda of Regulations published in April 25, 1988 (53 FR 13854, 13872) under Executive Order 12291 and the Regulatory Flexibility Act.

Under 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the undersigned hereby certifies that this rule would not have a significant economic impact on a substantial number of small entities. Congress provided several specific exemptions from the Act, and from the registration requirements of the Act, for identified small entities. In 15 U.S.C. 1702(c), Congress also directed the Department to create, by regulation, additional exemptions for small entities whose offerings are of a small amount or limited character. This proposed exemption is being promulgated pursuant to that authority.

The Catalog of Federal Domestic Assistance Program number is 14.801.

The information collection requirements contained in this rule have been approved by the Office of Management and Budget, and assigned approval number 2502-0243.

List of Subjects in 24 CFR Part 1710

Consumer protection, Land sales, Reporting and recordkeeping requirements.

Accordingly, 24 CFR Part 1710 is proposed to be amended as follows:

PART 1710—LAND REGISTRATION

1. The authority citation for 24 CFR Part 1710 would be revised to read as follows:

Authority: Sec. 1419, Interstate Land Sales Full Disclosure Act, 15 U.S.C. 1718; sec. 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

2. Section 1710.1 is proposed to be amended by adding a new term in alphabetical order to read as follows:

§ 1710.1 Definitions.

* * * * *

"Site" means a group of contiguous lots whether such lots are actually divided or proposed to be divided. Lots are considered to be contiguous even though contiguity may be interrupted by a road, park, small body of water, recreational facility or any similar object.

* * * * *

3. A new § 1710.15 is proposed to be added to read as follows:

§ 1710.15 Regulatory Exemption—Multiple Site Subdivision—Determination Required.

(a) *General.* (1) The sale of lots contained in multiple sites of fewer than 100 lots each, offered pursuant to a single common promotional plan is exempt from the registration requirements.

(2) For purposes of this exemption, the sale of lots in an individual site that exceeds 99 lots is not exempt from registration. Likewise, the sale of lots in a site containing fewer than 100 lots, where the developer either owns adjacent land or holds an option, or other evidence of intent, to acquire adjacent land which, when taken cumulatively, would or could result in one site of 100 or more lots, is not exempt from registration. Furthermore, the sale of lots that are within a subdivision established by a separate developer for the purpose of making lot sales, are not exempt from registration by this provision.

(b) *Eligibility Requirements.* The sale of each lot must meet the following requirements to be eligible for this exemption.

(1) The lot is sold "as is" with all advertised improvements and/or amenities completed and in the condition advertised.

(2) The lot is in conformance with all local codes and standards.

(3) The lot is accessible, both physically and legally, by a road suitable for use by automobile.

(4) At the time of closing, a title insurance binder or title opinion reflecting the condition of title must be issued to the purchaser showing that, subject only to exceptions which are approved in writing by the purchaser at the time of closing, marketable title is vested in the seller.

(5) Each contract—

(i) Contains a non-waivable provision giving the purchaser the right to revoke the contract until midnight of the seventh calendar day following the date the purchaser signed the contract. If the purchaser is entitled to a longer revocation period by operation of state or local law, that period becomes the Federal revocation period and the contract must reflect the requirement of the longer period;

(ii) Obligates the developer to deliver, within 180 days, a warranty deed (or its equivalent under local law) for the lot which at the time of delivery is free from any monetary liens or encumbrances; and

(ii) Contains a provision giving the purchaser the right to revoke the contract within two years from the date of sale if a "Lot Information Statement" (see below) is not delivered to the purchaser before he or she signs the contract.

(6) The purchaser or purchaser's spouse makes a personal on-the-lot inspection of the lot to be purchased before signing a contract.

(7) The purchaser's payments are deposited in an escrow account independent of the developer until a deed is delivered.

(8) Prior to the sale the developer discloses in a written statement to the purchaser all liens, reservations, taxes, assessments, easements and restrictions applicable to the lot purchased.

(9) Prior to the sale the developer provides in a written statement the name, address and telephone number of the local governmental agency or agencies from which information on permits or other requirements for water, sewer, electrical, heating fuel and telephone installations can be obtained. The statement will also contain the name, address and telephone number of a company or public utility which would or could provide the foregoing services.

(10) The lot sale must comply with the anti-fraud provisions of 24 CFR 1710.4 (b) and (c) of the sales practices and standards in 24 CFR 1715.10 through 1715.28.

(11) A copy of the "Lot Information Statement" in the form shown below, typed or printed in at leat 10 point font, will be furnished to, and acknowledged by, the purchaser prior to the signing of any contract or purchase agreement. A copy of the acknowledgement will be maintained by the developer for three years and will be made available to OILSR upon request. The Statement will contain the information required by paragraphs (b)(9) and (b)(10) of this section as well as all other information required by the form. If the Statement is not delivered as required, the purchase contract may be revoked and a full refund paid, at the option of the purchaser, within two years of the signing date, and the purchase contract will clearly provide this right.

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LOT INFORMATION STATEMENT

IMPORTANT: READ CAREFULLY BEFORE SIGNING ANYTHING

The developer has obtained a regulatory exemption from registration under the Interstate Land Sales Full Disclosure Act. One requirement of that exemption is that you must receive this Statement prior to the time you sign an agreement (contract) to purchase a lot.

RIGHT TO CANCEL: Your contract gives you the right to cancel your contract and receive a full refund for seven days following the date you sign your contract. (Enter the longer period if required by state or local law.)

RISK OF BUYING LAND: There are certain risks in purchasing real estate that you should be aware of. The following are some of those risks:

The future value of land is uncertain and dependent upon many factors. DO NOT expect all land to automatically increase in value.

Any value which your lot may have will be affected if roads, utilities and/or amenities cannot be completed or maintained.

Any development will likely have some impact on the surrounding environment. Development which adversely affects the environment may cause governmental agencies to impose restriction on the use of the land.

In the purchase of real estate, many technical requirements must be met to assure that you receive proper title and that you will be able to use the land for its intended purpose. Since this purchase involves a major expenditure of money, it is recommended that you seek professional advice before you obligate yourself.

If adequate provisions have not been made for maintenance of the roads or if the land is not served by publicly maintained roads, you may have to maintain the roads at your expense.

If the land is not served by a central sewage system and/or water system, the purchaser should contact the local authorities to determine whether a permit will be given for an on-site sewage disposal system and/or well and whether there is an adequate supply of water. The purchaser should also become familiar with the requirements for, and the cost of, obtaining electrical service to the lot.

DEVELOPER INFORMATION:

Developer's Name : _____

Address : _____

_____

Telephone Number: _____

LOT INFORMATION:

Lot Location: _____

(Enter a statement disclosing all liens, reservations, taxes, assessments, easements and restrictions applicable to the lot. A copy of the restrictions may be attached in lieu of recitation.)

Listed below are contact points for determining permit requirements, if any, and approximate costs and availability for the listed services:

	NAME, ADDRESS AND TELEPHONE NUMBER OF:	
	GOVERNMENTAL AGENCY	COMPANY OR PUBLIC UTILITY
WATER.....		
SEWER.....		
ELECTRICITY.....		

If misrepresentations are made in the sale of this lot to you, you may have rights under the Interstate Land Sales Full Disclosure Act. If you have evidence of any scheme, artifice or device used to defraud you, you may wish to contact:

Interstate Land Sales Registration Division
HUD Building - Room 6278
451 Seventh Street, S.W.
Washington, D.C. 20410

- -

RECEIPT FOR LOT INFORMATION STATEMENT

Received by: _____ Date: _____

Street Address: _____

City: _____ State: _____ Zip: _____

Name of Salesperson: _____
(Print or Type)

_____
(Signature)

(c) Request for Multiple Site Subdivision Exemption. (1) The developer must file a request for the Multiple Site Subdivision Exemption in the following format. The request must be accompanied by a filing fee of $500 and a sample Lot Information Statement

REQUEST FOR MULTIPLE SITE EXEMPTION

Developer:

Name : _____
Address : _____
_____
Telephone No.: _____

Agent:

Name : _____
Address : _____
_____
Telephone No.: _____

(Insert a description of the type of lots to be sold, the state and counties where intended sales will take place and a general description of the developer's method of operation.)

I affirm that I am, or will be, the developer of the property and/or method of operation described above.

I affirm that the lots in said property will be sold in compliance with all of the requirements of 24 CFR 1710.15.

I further affirm that the statements contained in all documents submitted with this request for an Exemption Order are true and complete.

Date : _____

Signature: _____

Title : _____

WARNING: 18 U.S.C. 1001 Provides, among other things, that whoever knowingly and willingly makes or uses a document or writing containing any false, fictitious, or fraudulent statement or entry, in any matter within the jurisdiction of any department or agency of the United States, shall be fined not more than $10,000 or imprisoned for not more than 5 years or both.

BILLING CODE 4210-27-C

(2) This exemption will become effective upon issuance of an Exemption Order by the Secretary.

(d) *Annual Report.* (1) By January 31 of each year the developer will send a report to the Secretary listing each site and its location available for sale pursuant to the exemption during the preceding year and indicate the number of lot sales made in each site. The report will describe any changes in the information provided in the Request for the Multiple Site Subdivision Exemption or contain a statement that there are no changes.

(2) The Annual Report must be accompanied by a filing fee of $100.

(3) The Annual Report must be signed and dated by the developer, attesting to its completeness and accuracy.

(4) Failure to submit the Annual Report will automatically terminate eligibility for the exemption as of the Report due date.

(e) *Termination.* If, subsequent to the issuance of an Exemption Order, the Secretary has reasonable grounds to believe that exemption from the registration requirements in the particular case is not in the public interest, the Secretary may, after issuing a notice and giving the respondent an opportunity to request a hearing within fifteen days of receipt of the notice, terminate the exemption order. The basis for issuing a notice may be apparent omissions or misrepresentations in the documents submitted to the Secretary, the conduct of the developer or agent, such as unlawful conduct or insolvency, or adverse information about the real estate that should be disclosed to purchasers. Proceedings will be governed by 24 CFR 1720.238.

(Approved by the Office of Management and Budget under OMB approval number 2502-0243)

Dated: July 6, 1988.

James E. Schoenberger,

General Deputy Assistant Secretary for Housing, Federal Housing Commissioner.

[FR Doc. 88-18318 Filed 8-11-88; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 925

Missouri Permanent Regulatory Program; Public Comment Period and Opportunity for Public Hearing on Proposed Amendments

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

ACTION: Proposed rule.

SUMMARY: OSMRE is announcing the receipt of proposed amendments to the Missouri permanent regulatory program (hereinafter referred to as the Missouri program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendments pertain to its alternative bonding system, the two-acre exemption repeal, prime farmland grandfather provisions, and the hydrologic balance for underground mining. If approved, the amendments will become part of the State's permanent regulatory program.

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

DATES: Written comments must be received on or before 4:00 p.m. September 12, 1988. If requested, a public hearing on the proposed amendments will be held on September 6, 1988. Requests to present oral testimony at the hearing must be received on or before 4:00 p.m., on August 29, 1988.

ADDRESSES: Written comments should be mailed or hand delivered to Mr. William J. Kovacic at the address listed below. Copies of the Missouri program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive, free of charge, one copy of the proposed amendments by contacting OSMRE's Kansas City Field Office.

Mr. William J. Kovacic, Kansas City Field Office, Office of Surface Mining Reclamation and Enforcement, 1103 Grand Avenue, Room 502, Kansas City, Missouri 64106, Telephone: (816) 374-5527.

Office of Surface Mining Reclamation and Enforcement, Administrative Record Office, Room 5131, 1100 L Street NW., Washington, DC 20240, Telephone: (202) 343-5492

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

FOR FURTHER INFORMATION CONTACT: Mr. William J. Kovacic, Director, Kansas City Field Office at the address or telephone number listed in "ADDRESSES.".

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Interior approved the Missouri program on November 21, 1980. Information regarding the general background of the Missouri program, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Missouri program can be found in the November 21, 1980, **Federal Register** (45 FR 77017). Subsequent actions taken with regard to the program and amendments can be found at 30 CFR 925.15 and 925.16.

II. Proposed Amendments

On July 8, 1988, (Administrative Record No. MO-388) Missouri submitted proposed amendments to its permanent regulatory program under SMCRA. Missouri submitted proposed amendments in response to a January 30, 1986, letter that OSMRE sent to Missouri under 30 CFR Part 732 concerning the State's alternative bonding system. The amendment contains revisions that modify sections of the Revised Statutes of Missouri (RSMo) at 444.805 Definitions, 444.830 Bond Required, 444.950 Pit Reclamation, 444.960 Coal Mine Land Reclamation Fund, and 444.965 Fund Assessments.

Missouri submitted proposed amendments in response to Pub. L. 100-34 and a June 4, 1987, **Federal Register** notice (52 FR 21228) by OSMRE that the exemption from regulation of surface mining operations on two acres or less would no longer be allowed. The amendment contains revisions that modify Missouri's statutes at RSMo sections 444.535 subsection 7 and 444.815 subsection 6 to delete its two-acre exemption.

At Missouri's own initiative, the State revises its regulations at 10 CSR 40-2.110(1)(B) Prime Farmland Requirements and 10 CSR 40-6.060 Special Category Permits to reinstate the

grandfather provisions for prime farmland under both the interim and permanent programs. At its own initiative, the State revises its regulations at 10 CSR 40-3.200(2)(B) Underground Hydrologic Balance to delete the variance provisions related to the effluent limitations of surface disturbed areas.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSMRE is now seeking comment on whether the amendments proposed by Missouri satisfy the applicable program approval criteria of 30 CFR 732.15. If the amendments are deemed adequate, they will become part of the Missouri program.

Written Comments

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

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under "**FOR FURTHER INFORMATION CONTACT**" by 4:00 p.m. August 29, 1988. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

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

The public hearing will continue on the specified date until all persons scheduled to comment having been heard. Persons in the audience who have been scheduled to comment who wish to do so will be heard following those scheduled. The hearing will end after all persons scheduled to comment and persons present in the audience who wish to comment have been heard.

Public Meeting

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

List of Subjects in 30 CFR Part 925

Coal Mining, Intergovernmental relations, Surface mining, Underground mining.

Richard E. Dawes,

Acting Assistant Director, Western Field Operations.

Date: July 22, 1988.

[FR Doc. 88-18245 Filed 8-11-88; 8:45 am]

BILLING CODE 4310-05-M

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30 CFR Part 946

Reopening of Public Comment Period and Opportunity for Public Hearing of Proposed Amendments to the Virginia Permanent Regulatory Program

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

ACTION: Proposed rule.

SUMMARY: By letter dated December 22, 1987, Virginia submitted program amendments to the Virginia permanent regulatory program (herein after referred to as the Virginia Program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). These amendments, if approved, will establish alternate standards for permitting, bonding, and reclamation on surface coal mining and reclamation operations which remine areas affected before the effective date of SMCRA. OSMRE published a notice announcing receipt of these amendments and opening of the public comment period in the February 19, 1988, **Federal Register** (53 FR 5002-5004). The public comment period ended March 21, 1988.

During the review of Virginia's proposed amendments, OSMRE identified several concerns. These were relayed to the State by letter dated June 13, 1988, (Virginia Administrative Record Number VA 689). By letter dated July 12, 1988, (Virginia Administrative Record Number VA 694), Virginia resubmitted parts of the proposed amendments with corrections and clarifications, and expressed its intent to submit additional information at a late date.

Accordingly, OSMRE is reopening and extending the public comment period of Virginia's December 22, 1987, proposed program amendments as revised July 12, 1988. This action is being taken to provide the public with an opportunity to reconsider the adequacy of the purposed amendments considering the additional information.

DATES: Written comments must be received on or before 4:00 p.m. on September 12, 1988. If requested, a public hearing on the proposed amendments will be held on September 6, 1988; requests to present testimony at the hearing must be received on or before 4:00 p.m. August 29, 1988.

ADDRESSES: Written comments and requests to testify at the hearing should be mailed or hand delivered to Mr. Willian R. Thomas, Director, Big Stone Gap Field Office at the first address listed below. If a hearing is requested, it will be held at the same address.

Copies of the Virginia program, proposed amendments and all written comments received in response to this notice will be available for review at the location listed below during normal business hours Monday through Friday, excluding holidays. Each proposed amendment by contacting the OSMRE Big Stone Gap Field Office.

Office of Surface Mining Reclamation and Enforcement, Big Stone Gap Field Office, P.O. Box 626, Powell Valley Square Shopping Center, Room 220, Route 23, Big Stone Gap, Virginia 24219, Telephone (703) 523-4303.

Office of Surface Mining Reclamation and Enforcement, Administrative Record Office, Room 5315, 1100 L Street NW., Washington, DC 20240, Telephone (202) 343-5492.

Virginia Division of Mined Land Reclamation, P.O. Drawer U, 622 Powell Avenue, Big Stone Gap, Virginia 24219, Telephone (703) 523-2925.

FOR FURTHER INFORMATION CONTACT: Mr. William R. Thomas, Director, Big Stone Gap Field Office, Telephone (703) 523-4303.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Interior approved the Virginia program on December 15, 1981. Information pertinent to the general background and revisions to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval can be found in the December 15, 1981 **Federal Register** (46 FR 61085-61115). Subsequent actions concerning the conditions of approval and proposed amendments are identified at 30 CFR 946.12, 946.13, 946.15, and 946.16.

II. Discussion of Amendments

A discussion of the originally proposed amendments is contained in the February 19, 1988, **Federal Register** (53 FR 5002-5004). Following receipt of the OSMRE June 13, 1988, letter detailing concerns identified during review of the proposal, Virginia resubmitted the proposal with corrections and clarifications by letter dated July 12, 1988, (Administrative Record No. VA 694). The resubmission is briefly described below.

1. In a meeting on May 12, 1988, Virginia advised OSMRE that the proposal would be resubmitted in phases by four priorities. These priorities were established as:

a. Definitions, permitting requirements for remining (except waste pile reprocessing and remnant remining), special remining performance standards, and policy on implementing no cost Abandoned Mined Land (AML) contracts;

b. Reprocessing of coal waste piles—permitting and performance standards;

c. Bonding alternatives and civil penalty credits; and

d. Remnant remining permitting and performance standards.

This submittal is considered the first phase.

2. The proposed definition for "Reprocessing Coal Mine Waste" has been modified in response to OSMRE's concern that the originally proposed definition appeared to allow redisturbance and reclamation of coal mine waste piles created after the effective date of SMCRA under proposed standards less stringent than those in effect at the time such piles were created. Definitions for "abatement plan", "actual improvement", "baseline pollution load", and "pollution abatement area" were deleted from this amendment as proposed changes to Virginia's regulations section 480-03-19.700.5. These definitions were approved in the June 16, 1988, **Federal Register** (53 FR 22479-22484) as part of an amendment allowing alternative effluent limitations on operations which reaffect previously mined lands with existing pollutional discharges.

3. Proposed section 480-03-19.830.14 has been modified to require bond on permitted spoil disposal areas associated with remining operations to be calculated by the applicant based upon the degree of difficulty of reclamation. The proposal will exempt such disposal sites when no coal is removed from the disposal area and no existing pollutional discharges are present.

4. Proposed section 480-03-19.831.2 has been modified to include the requirement that all program performance standards, including standards for special categories of mining, shall apply to remining operations except as provided by proposed Part 480-03-19.831.

5. Proposed section 480-03-19.831.12 has been modified in response to OSMRE's concerns that the original proposal did not require a demonstration of the stability of any remaining highwall remnants, the use of all reasonably available spoil, and drainage controls to minimize erosion and water pollution both on and off site. Information was also submitted in justification of the proposed limit of backfilled and regraded slopes no greater than 2H:1v on previously mined lands and stability of backfilled and regraded areas.

6. Proposed 480-03-19.831.13 has been modified to clarify that only excess spoil from remining operations may be placed on pre-existing benches approved as disposal areas. This section has also been modified to require design and certification of the plans for disposal, with exception of the standard for lift thickness. Also, it is proposed to reduce the number of inspections by a registered professional engineer during construction of these fills provided certain conditions exist at the construction site and specific requirements are covered by the design.

7. Proposed 480-03-19.831.14 is being revised to clarify that only excees spoil may be used to reclaim areas outside the permit. These areas will include lands under another permit, under contract for reclamation under Virginia's AML program, under contract for reclamation due to bond forfeiture, affected by government financed construction projects, or under a no-cost AML contract with Virginia. Part of the resubmittal concerns detailed policy and procedures for implementation of no-cost AML contracts.

8. Proposed 480-03-19.831.17 has been modified to provide additional requirements pertaining to the continued use, modification, maintenance, and reclamation of existing sumps, depressions, or ponds utilized for drainage and sediment control on remining operations.

9. Proposed 480-03-19.831.18 has been modified to clarify that vegetative ground cover cannot be less than that existing before remining operations occur, on 75 percent, whichever is greater. Additional information to justify 75 percent ground cover as sufficient to control erosion was also submitted.

10. Proposed 480-03-19.831.21 has been modified to remove the provision allowing the release of bond for reclamation bond credits.

11. The following proposals are not being resubmitted at this time. Virginia has requested that OSMRE defer its decision to approve or deny these proposals until revised versions can be submitted at a later date:

a. Section 480-03-19.831.12—Reprocessing Coal Mine Waste Permit Requirements,

b. Section 480-03-19.831.15—Remining Reclamation Bond Credits,

c. Section 480-03-19.831.16—Reprocessing of Coal Mine Waste (performance standards),

d. Part 480-03-19.832—Remining Civil Penalty Options,

e. Part 480-03-19-835—Remnant Remining, and

f. Part 480-03-19.836—Remnant Remining Performance Standards.

12. Virginia is asking approval of the following proposed amendments as originally submitted on December 22, 1987:

a. Section 480-03-19.830.10—Minimum Permit and Environmental Resources Information Requirements (remining operations),

b. Section 480-03-19.830.11—Remining Operation/Reclamation Plan.

c. Section 480-03-19.831.19—Existing Roads, and

d. Parts 480-03-19.833 and 480-03-19.834—Recodification of approved section 480-03-19.785.19 and Part 480-03-19.825 of the Virginia program.

III. Public Comments Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSMRE is now seeking comment on whether the amendments proposed by Virginia satisfy the applicable program approval criteria of 30 CFR 732.15. If the amendments are deemed adequate, they will become part of the Virginia program.

Written Comments

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

Public Hearing

Persons wishing to comment at the public hearing should contact the person

listed under "**FOR FURTHER INFORMATION CONTACT**" by close of business on August 29, 1988. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

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

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

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting, rather than a public hearing, may be held.

Persons wishing to meet with OSMRE representatives to discuss the proposed amendments may request a meeting at the Big Stone Gap Field Office by contacting the person listed under "FOR FURTHER INFORMATION CONTACT". All such meetings will be open to the public and, if possible, notices of meetings will be posted in advance at the locations listed under "**ADDRESSES**". A written summary of each public meeting will be made part of the Administrative Record.

List of Subjects in 30 CFR Part 946

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Date: July 27, 1988.

Carl C. Close,

Assistant Director, Eastern Field Operations.

[FR Doc. 88-18244 Filed 8-11-88; 8:45 am]

BILLING CODE 4310-05-M

POSTAL SERVICE

39 CFR Part 111

Nonmailability of Etiologic Agents; Extension of Time for Comment

AGENCY: Postal Service.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On June 24, 1988, the Postal Service published in the **Federal Register** (53 FR 23775) a proposed rule change intended to prohibit the mailing of etiologic agents, or materials reasonably believed to contain them which are required to bear an Etiologic Agents/Biomedical Material label under Department of Transportation and Department of Health and Human Services rules. The Postal Service requested comments by August 8, 1988. In response to requests for additional time, the Postal Service is extending the comment period to August 22, 1988.

DATE: Comments on the proposed rule change must be received on or before August 22, 1988.

ADDRESS: Written comments should be mailed or delivered to the Director, Office of Classification and Rates Administration, Rates and Classification Department, Room 8430, 475 L'Enfant Plaza West, SW, Washington, DC 20260-5360. Copies of all written comments will be available for inspectiona nd photocopying between 9:00 a.m. and 4:00 p.m., Monday through Friday, in Room 8430, at the above address.

FOR FURTHER INFORMATION CONTACT: F.E. Gardner, (202) 268-5178.

Fred Eggleston,

Assistant General Counsel, Legislative Division.

[FR Doc. 88-18282 Filed 8-11-88; 8:45 am]

BILLING CODE 7710-12-M

39 CFR Part 111

Unauthorized Use of Postage Meters

AGENCY: Postal Service.

ACTION: Withdrawal of proposed rule.

SUMMARY: On the basis of comments received, which are summarized in the Supplementary Information, and for other reasons, the Postal Service is withdrawing the proposed rule to require mailers preparing metered mail for others to furnish certain additional information with the mailing.

FOR FURTHER INFORMATION CONTACT: F.E. Gardner (202) 268-5178.

SUPPLEMENTARY INFORMATION: On February 23, 1988, the Postal Service published a proposed rule, which would have required a commercial mailer preparing metered mail for others to provide a list of the meter serial numbers, names of meter holders, number of pieces mailed, and rate per piece for each meter used in the mailing, to help guard against misuse of meters. 53 FR 5282.

Approximately 85 comments were received in response to the proposed rule. Most commenters said they would incur excessive administrative costs if the proposed rule were implemented. Several commenters said it would be impossible to provide the information when pieces are premetered by the owner of the mail and some of the pieces are given to a commercial mailer to presort. They stated that the owners of the mail normally presort and enter most of their own mail, often using several metering runs at different rates during the same day. The residual volume, which does not qualify for presort rates, is then given to a commercial presort mailer to presort it with other mail in order to qualify for the lower presort rates.

In view of these comments, and the fact that other measures were implemented in April, 1988, to help curb unauthorized use of postage meters, the Postal Service has decided to withdraw the proposed rule. The Postal Service will continue to monitor its current procedures, and will consider appropriate adjustments as needed to prevent misuse of postage meters.

Fred Eggleston,

Assistant General Counsel, Legislative Division.

[FR Doc. 88-18283 Filed 8-11-88; 8:45 am]

BILLING CODE 7710-12-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL-3420-5]

National Oil and Hazardous Substances Contingency Plan; the National Priorities List

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of Intent to Delete a Site from the National Priorities List (NPL); Request for Comments.

SUMMARY: EPA announces its intent to delete a site from the NPL and requests public comment. The site is the Toftdahl Drums site in Brush Prairie, Washington. EPA has determined that the appropriate remedy has been completed and that the site presents no further hazard to public health or the environment. The site meets the criteria for deletion provided in the National Oil and Hazardous Substances Contingency Plan (NCP) as published in the **Federal Register** on November 20, 1985 (50 FR 47912), § 300.66(c)(7). The NPL is Appendix B to the NCP, which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA).

DATE: Comments concerning the Toftdahl Drums site may be submitted on or before September 12, 1988.

ADDRESSES: Comments should be mailed to Judi Schwarz, Superfund Branch, U.S. EPA Region 10, 1200 Sixth Avenue, Mail Stop HW-113, Seattle, Washington 98101. Information on the site is available in the regional and local public dockets. The regional docket is available for viewing at the U.S. EPA Region 10 Library, 1200 Sixth Avenue, 10th Floor, Seattle, Washington, (206) 442-1289, during business hours. The local docket is available for viewing at the Southwest Washington Health District (Attn: Gary Bickett), 2000 Fort Vancouver Way, Vancouver, Washington, 98663, (206) 695-9215, during business hours.

FOR FURTHER INFORMATION CONTACT: Judi Schwarz, Superfund Branch, U.S. EPA Region 10, 1200 Sixth Avenue, Mail Stop HW-113, Seattle, Washington 98101, (206) 442-2684.

SUPPLEMENTARY INFORMATION: EPA announces its intent to delete the Toftdahl Drums site from the NPL and requests comments on this deletion. This site meets the criteria for deletion provided in the NCP as published in the **Federal Register** on November 20, 1985 (50 FR 47912), § 300.66(c)(7).

The Toftdahl Drums site is a rural property about fifteen acres in size located in Clark County about four miles east-southeast of Battleground, Washington. The owner of the property was alleged to have had delivered to the site in the early 1970s one hundred to two hundred drums containing unknown amounts of industrial waste material. His intent was to clean and sell the drums, but about fifty drums with waste residues were buried on site. The drums were rediscovered in the mid-1970s by the new owner of a portion of the property. In 1982, the original property owner removed approximately thirty-eight drums to a local landfill.

The Washington Department of Ecology (Ecology) was first notified about the possible presence of buried drums in 1982. In 1983, an EPA contractor conducted a site investigation in which the remains of six drums were found and sampled. Samples of nearby soil, groundwater, drinking water, and surface water were also taken. Traces of several organic compounds were detected in the groundwater, but no significant contamination which could be attributed to the site was found. In May 1984, Ecology nominated this site for inclusion on the NPL, and in June 1986, this site appeared on the final NPL.

In 1984, Ecology took soil samples from the alleged drum cleaning area. No organic contaminants were detected, and no gross quantities of heavy metals were found. Using state monies, Ecology's contractor conducted an additional investigation in late 1984 to identify other potential drum burial locations. An Initial Remedial Measure was started in June 1985 by a state contractor to remove the remaining drums and soil contamination. The remains of five crushed drums, parts of additional drums, and forty cubic yards of contaminated soils were removed and disposed of at a Resource Conservation and Recovery Act (RCRA) permitted hazardous waste landfill. A Remedial Investigation (RI) was initiated in December 1985 by a state contractor and was completed in July 1986.

The environmental sampling and chemical analysis program undertaken during the RI showed no significant or extensive contamination of surface soil, surface water, or groundwater at the site. Pre-RI chemical data for drum/waste samples and adjacent soil samples showed that the drum cleaning and disposal activities at the Toftdahl site did introduce some contaminants at the site. Priority pollutants which had been detected at least one time in the drum/waste or nearby soil samples were used as indicator constituents in the RI. These included metals, volatile organic compounds, base neutral organic compounds, cyanides, and polychlorinated biphenyls. While several of these priority pollutants were detected in the RI sampling and analysis program, the concentration of such contamination was very small and in most cases could not be reliably differentiated from background values or laboratory-introduced variability. Most of the potentially waste-related indicator constituents that have been detected have not been consistently detected over repeated sampling events at the site. Whether related or not, the magnitude of the contamination is extremely small, does not exceed any applicable or relevant and appropriate federal public health or environmental standard, and does not appear to be a potential source for public health risks. No RCRA hazardous wastes nor Ecology dangerous wastes are present at the site. Federal drinking water standards are met at the downgradient private wells for all waste indicator constituents. No substances regulated by the Toxic Substances Control Act have been found at the site.

There are no longer any access controls at the site. A fence had surrounded the drum storage area. After the drums were removed in 1985, the fence was no longer needed and was removed as requested by nearby residents. Some paint chip-like material is visible at several scattered locations at the site. Samples analyzed during the RI demonstrate that these are not RCRA hazardous wastes nor Ecology dangerous waste.

A local public comment period on the No Action Alternative in the RI report was held from August 19, 1986, through September 19, 1986. Two comments were received. A detailed report of those comments and agency response is available in the Responsiveness Summary of the Record of Decision (ROD) at the EPA docket offices listed above. The ROD was signed by the Regional Administrator on September 30, 1986.

EPA, with concurrence of the state of Washington, has determined that all appropriate fund-financed response under CERCLA at the Toftdahl Drums site has been completed, and has determined that no further cleanup by responsible parties is appropriate.

As a precautionary measure, Ecology agrees to continue performance monitoring by sampling and analyzing nearby private residential and monitoring wells semiannually for five years, and then annually for ten additional years, subject to funding by the legislature of the state of Washington.

Deletion of a site from the NPL does not preclude eligibility for subsequent EPA response actions. Section 300.66(c)(8) of the NCP states that EPA response actions may be taken at sites that have been deleted from the NPL if future conditions warrant such action.

Concurrence:

Robie G. Russell,

Regional Administrator.

[FR Doc. 88-16889 Filed 8-11-88; 8:45 am]

BILLING CODE 6560-50-M

Notices

Federal Register
Vol. 53, No. 156
Friday, August 12, 1988

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.

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Meeting

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given in accordance with the regulations of the Advisory Council on Historic Preservation, "Urban Development Action Grant Program: Historic Preservation Requirements" (36 CFR Part 801), that a panel of five members of the Council will meet on August 24, 1988, to consider the proposed demolition of the American Can Company complex in Baltimore, Maryland, and the construction of a new retail center on the site. It has been determined that this undertaking, for which the City of Baltimore has applied for and received an Urban Development Action Grant from the U.S. Department of Housing and Urban Development, will adversely affect the Canton Historic District, a property listed in the National Register of Historic Places.

The panel will meet in Baltimore, Maryland, at St. Casimir's Church meeting hall (Jubilee Room), at O'Donnell and South Lakewood, beginning at 3:30 p.m. Oral statements from the public will be heard from 6:30 to 8:30 p.m.

The panel welcomes written and oral statements from concerned parties. Written statements should be submitted to the Executive Director of the Council by August 17. Persons wishing to make oral statements should contact the Executive Director by August 22, Attention: Anne Weinheimer (202) 786-0505. Oral presentations must be limited to three (3) mintues. Priority will be given to those persons who have indicated prior to the meeting their desire to speak.

The Council was established by the National Historic Preservation Act to advise the President and Congress on matters relating to historic preservation and to comment upon Federal, federally assisted, and federally licensed undertakings having an effect upon properties listed in or eligible for listing in the National Register of Historic Places.

Note: The meeting of the Council are open to the public. If you need special accommodation due to a disability, please contact the Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue NW., Suite 809, Washington, DC 20004 (202-786-0505).

FOR FURTHER INFORMATION CONTACT: Additional information concerning the meeting schedule and location or the submission of statements is available from the Executive Director, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue NW., Suite 809, Washington, DC 20004, Attention: Don Klima or Anne Weinheimer (202) 786-0505.

Date: August 8, 1988.

John M. Fowler,

Acting Executive Director.

[FR Doc. 88-18233 Filed 8-11-88; 8:45 am]

BILLING CODE 4310-10-M

DEPARTMENT OF COMMERCE

International Trade Administration

[A-588-704]

Antidumping Duty Order of Sales at Less Than Fair Value; Brass Sheet and Strip From Japan

ACTION: Notice.

SUMMARY: In separate investigations concerning brass sheet and strip from Japan, the United States Department of Commerce (the Department) and the United States International Trade Commission (the ITC) have respectively determined that brass sheet and strip from Japan are being sold at less than fair value and that sales of brass sheet and strip from Japan are materially injuring a U.S. industry. Therefore, based on these findings, all unliquidated entries, or warehouse withdrawals of brass sheet and strip for consunption from Japan, made on or after February 1, 1988, the date on which the Department published its "Preliminary Determination" notice in the Federal Register, will be liable for the possible assessment of antidumping duties. Further, a cash deposit of estimated antidumping duties must be made on all such entries, and withdrawals from warehouse, for consumption made on or after the date of publication of this antidumping duty order in the Federal Register.

EFFECTIVE DATE: August 12, 1988.

FOR FURTHER INFORMATION CONTACT: Gregory G. Borden (202) 377-3003 or Louis Apple (202) 377-1769, Office of Investigations, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION: The products covered by this order are brass sheet and strip, other than leaded brass and tin brass sheet and strip, as provided for in the *Tariff Schedules of the United States Annotated* (TSUSA) item numbers 612.3960, 612.3982, and 612.3986. The corresponding Harmonized System (HS) numbers are 7409.21.0050, 7409.21.0075, 7409.29.0050, and 7409.29.0075. The chemical compositions of the products covered by the investigation are currently those of the Copper Development Association (C.D.A.) 200 series or the Unified Numbering System (U.N.S.) C20000 series. Products whose chemical compositions are covered by other C.D.A. or U.N.S. series are not covered by this investigation.

In accordance with section 735(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1673d(a)) (the Act), on June 15, 1988, the Department made its final determination that brass sheet and strip from Japan are being sold at less than fair value (53 FR 23296, June 21, 1988). On July 29, 1988, in accordance with section 735(d) of the Act, the ITC notified the Department that such imports materially injure a U.S. industry.

Therefore, in accordance with section 736 of the Act (19 U.S.C. 1673e), the Department directs United States Customs officers to assess, upon further advice by the administering authority pursuant to section 736(a)(1) of the Act (19 U.S.C. 1673e(a)(1)), antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all entries of brass sheet and strip from Japan. These antidumping duties will be assessed on all unliquidated entries of brass sheet and strip entered, or

withdrawn from warehouse, for consumption on or after February 1, 1988, the date on which the Department published its "Preliminary Determination" notice in the **Federal Register** (53 FR 2771).

On and after the date of publication of this notice, United States Customs officers must require, at the same time as importers would normally deposit estimated duties on this merchandise, a cash deposit equal to the estimated weighted-average antidumping duty margins noted below:

Manufacturers/Producers/Exporters	Weighted-average margin percentages
Nippon Mining Co., Ltd.	57.98
Sambo Copper Alloy Co., Ltd.	13.30
Mitsubishi Shindoh Co., Ltd.	57.98
Kobe Steel	57.98
All others	45.72

This determination constitutes an antidumping duty order with respect to brass sheet and strip from Japan, pursuant to section 736(a) of the Act (19 U.S.C. 1673e) and § 353.48 of the Commerce Regulations (19 CFR 353.48). We have deleted from the Commerce Regulations Annex I of 19 CFR Part 353, which listed antidumping duty findings and orders currently in effect. Instead, interested parties may contact the Central Records Unit, Room B-099, Import Administration, for copies of the updated list of orders currently in effect.

This notice is published in accordance with section 736(a) of the Act (19 U.S.C. 1673e) and § 353.48 of the Commerce Regulations (19 CFR 353.48.)

August 5, 1988.

Jan W. Mares,

Assistant Secretary for Import Administration.

[FR Doc. 88-18306 Filed 8-11-88; 8:45 am]

BILLING CODE 3510-09-M

[A-421-701]

Antidumping Duty Order of Sales at Less Than Fair Value; Brass Sheet and Strip From the Netherlands

ACTION: Notice.

SUMMARY: In separate investigations concerning brass sheet and strip from the Netherlands, the United States Department of Commerce (the Department) and the United States International Trade Commission (the ITC) have determined that brass sheet and strip from the Netherlands are being sold at less than fair value and that sales of brass sheet and strip from the Netherlands are materially injuring a U.S. industry. Therefore, based on these findings, all unliquidated entries, or warehouse withdrawals of brass sheet and strip for consumption from the Netherlands, made on or after February 8, 1988, the date on which the Department published its "Preliminary Determination" notice in the **Federal Register**, will be liable for the possible assessment of antidumping duties. Further, a cash deposit of estimated antidumping duties must be made on all such entries, and withdrawals from warehouse, for consumption made on or after the date of publication of this antidumping duty order in the **Federal Register.**

EFFECTIVE DATE: August 12, 1988.

FOR FURTHER INFORMATION CONTACT: Mary S. Clapp (202) 377-1769, Office of Investigations, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION: The product covered by this order are brass sheet and strip, other than leaded brass and tin brass and strip, as provided for in the *Tariff Schedules of the United States Annotated* (TSUSA) item numbers 612.3960, 612.3982, and 612.3986. The corresponding Harmonized System (HS) numbers are 7409.21.0050, 7409.21.0075, 7409.29.0050, and 7409.29.0075. The chemical compositions of the products covered by the investigation are currently those of the Copper Development Association (C.D.A.) 200 series or the Unified Numbering System (U.N.S.) C20000 series. Products whose chemical compositions are covered by other C.D.A. or U.N.S. series are not covered by this investigation.

In accordance with section 735(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1673d(a)) (the Act), on June 15, 1988, the Department made its final determination that brass sheet and strip from the Netherlands are being sold at less than fair vaule (53 FR 23431, June 22, 1988). On July 29, 1988, in accordance with section 735(d) of the Act, the ITC notified the Department that such imports materially injure a U.S. industry.

Therefore, in accordance with section 736 of the Act (19 U.S.C. 1673e), the Department directs United States Customs officers to assess, upon further advice by the administering authority pursuant to section 736(a)(1) of the Act (19 U.S.C. 1673e(a)(1)), antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all entries of brass sheet and strip from the Netherlands. These antidumping duties will be assessed on all unliquidated entries of brass sheet and strip entered, or withdrawn from warehouse, for consumption on or after February 8, 1988, the date on which the Department published its "Preliminary Determination" notice in the **Federal Register** (53 FR 3612).

On and after the date of publication of this notice, United States Customs officers must require, at the same time as importers would normally deposit estimated duties on this merchandise, a cash deposit equal to the estimated weighted-average antidumping duty margins noted below:

Manufacturers/Producers/Exporters	Weighted-average margin percentages
Metallverken Nederland, B.V.	16.99
All others	16.99

This determination constitutes an antidumping duty order with respect to brass sheet and strip from the Netherlands, pursuant to section 736(a) of the Act (19 U.S.C. 1673e) and § 353.48 of the Commerce Regulations (19 CFR 353.48). We have deleted from the Commerce Regulations Annex I of 19 CFR Part 353, which listed antidumping duty findings and orders currently in effect. Instead, interested parties may contact the Central Records Unit, Room B-099, Import Administration, for copies of the updated list of orders currently in effect.

This notice is published in accordance with section 736(a) of the Act (19 U.S.C. 1673e) and § 353.48 of the Commerce Regulations (19 CFR 353.48.)

August 5, 1988.

Jan W. Mares,

Assistant Secretary for Import Administration.

[FR Doc. 88-18307 Filed 8-11-88; 8:45 am]

BILLING CODE 3510-05-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcement of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in the Hungarian People's Republic

August 9, 1988.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing limits.

EFFECTIVE DATE: August 16, 1988.

Authority: E.O. 11651 of March 3, 1972, as amended; sec. 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854)

FOR FURTHER INFORMATION CONTACT: Jerome Turtola, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION: During recent consultations between the Governments of the United States and the Hungarian People's Republic, agreement was reached to amend the current bilateral agreement to include specific limits for Categories 313 and 604.

A copy of the bilateral textile agreement is available from the Textiles Division, Economic Bureau, U.S. Department of State, (202) 647-1998.

A description of the textile categories in terms of T.S.U.S.A. numbers is available in the *Correlation:* Textile and Apparel Categories with the Tariff Schedules of the United States Annotated (see **Federal Register** notice 52 FR 47745, dated December 11, 1987).

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

James H. Babb,

Chairman, Committee for the Implementation of Textile Agreements.

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

August 9, 1988.

Commissioner of Customs
Department of the Treasury, Washington, DC 20229.

Dear Mr. Commissioner:

Under the terms of Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Arrangement Regarding International Trade of Textiles done at Geneva on December 20, 1973, as further extended on July 31, 1986; pursunat to the Bilateral Wool Textile Agreement of February 15 and 25, 1983, as amended, between the Governments of the United States and Hungarian People's Republic; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on August 16, 1988, entry into the United States for consumption of cotton and man-made fiber textile products in the following categories, produced or manufactured in Hungary and exported during the period which began on March 1, 1988 and extends through December 31, 1988, in excess of the following levels of restraint:

Category	10-mo. restraint limit
313	11,042,000 square yards.
604	1,250,000 punds.

Textile products in Categories 313 and 604 which have been exported to the United States prior to March 1, 1988 shall not be subject to this directive.

Textile products in Categories 313 and 604 which have been released from custody of the U.S. Customs Service under the provisions of 19 U.S.C. 1448(b) or 1484(a)(1)(A) prior to the effective date of this directive shall not be denied entry under this directive.

The restraint limits for Categories 313 and 604 are subject to adjustment in the future under the provisions of the current bilateral textile agreement between the Governments of the United States and the Hungarian People's Republic.

There are no charges to be made to the limits established in this directive for Categories 313 and 604 for the import period March 1 through 30, 1988. Charges will be made as data become available.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

James H. Babb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 88-18288 Filed 8-11-88; 8:45 am]

BILLING CODE 3510-DR-M

Issuance of a New Certification Stamp for Certain Cotton, Wool and Man-Made Fiber Sweaters Assembled in the Northern Mariana Islands (CNMI) From Imported Parts

August 9, 1988.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs authorizing the use of a new certification stamp.

EFFECTIVE DATE: August 15, 1988.

Authority: E.O. 11651 of March 3, 1972, as amended; sec. 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

FOR FURTHER INFORMATION CONTACT: Anne Novak, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212.

SUPPLEMENTARY INFORMATION: The Government of the United States and the Commonwealth of the Northern Mariana Islands (CNMI) agreed to amend the existing certification arrangement for cotton, wool and man-made fiber sweaters assembled in the CNMI and exported from the CNMI on or after August 15, 1988 to provide for the use of a new certification stamp which will include the standard nine-digit numbering system.

A description of the textile categories in terms of T.S.U.S.A. numbers is available in the CORRELATION: Textile and Apparel Categories with Tariff Schedules of the United States Annotated (see **Federal Register** notice 52 FR 47745, published on December 16, 1987). Also see 50 FR 8650, published on March 4, 1985, and 50 FR 36645, published on September 9, 1985.

James H. Babb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

August 9, 1988.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Mr. Commissioner: This directive amends, but does not cancel, the directive issued to you on February 27, 1985, as amended on September 4, 1985. That directive permitted entry of cotton, wool and man-made fiber sweaters in Categories 345, 445, 446, 645 and 646, determined by the U.S. Customs Service to be products of a foreign country or foreign territory and certified as assembled in the Commonwealth of the Northern Mariana Islands (CNMI).

Effective on August 15, 1988, you are directed to permit entry of shipments of cotton, wool and man-made fiber sweaters in Categories 345, 445, 446, 645 and 646, assembled in the CNMI, but not of CNMI origin, which are certified by authorities of the CNMI, and exported from the CNMI on or after August 15, 1988, using the new stamp and nine-digit numbering system.

The nine-digit numbering system shall begin with one numerical digit for the last digit of the calendar year, followed by the two character alpha country code specified by the International Organization for Standardization (ISO) (the code for the Commonwealth of the Northern Mariana Islands is "MP"), followed by six numerical digits.

Enclosed is a facsimile of a new certification stamp, allowing more space to include use of the standard nine-digit numbering system. This stamp replaces the one currently being used by the

Commonwealth of the Northern Mariana Islands.

Goods exported from the CNMI prior to August 15, 1988, that have been certified by the CNMI by using the old certification stamp shall not be denied entry for consumption, or withdrawal from warehouse for consumption, into the Customs territory of the United States (i.e., the 50 States, the District of Columbia and the Commonwealth of Puerto Rico), provided they are in accordance with previous requirements.

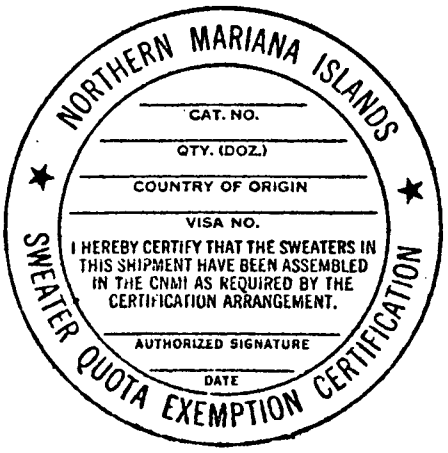
The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

James H. Babb,

Chairman, Committee for the Implementation of Textile Agreements.

Facsimile of New Certification Stamp for Textile Products From the CNMI



[FR Doc. 88-18289 Filed: 8-11-88; 8:45 am]

BILLING CODE 3510-DR-M

Amendment to the Export Visa Requirements for Certain Man-Made Fiber Textile Products From Pakistan

August 9, 1988.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs amending visa requirements.

EFFECTIVE DATE: August 15, 1988.

Authority: E.O. 11651 of March 3, 1972, as amended; sec. 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

FOR FURTHER INFORMATION CONTACT: Anne Novak, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212.

SUPPLEMENTARY INFORMATION: The visa requirements are being amended to include coverage of man-made fiber textile products in merged Categories 226/313, 613/614, 638/639 and 647/648, produced or manufactured in Pakistan and exported from Pakistan on and after January 1, 1988.

A copy of the current bilateral textile agreement is available from the Textiles Division, U.S. Department of State, (202) 647-1998.

A description of the textile categories in terms of T.S.U.S.A. numbers is available in the CORRELATION: Textile and Apparel Categories with Tariff Schedules of the United States Annotated (see **Federal Register** notice 52 FR 47745, published on December 16, 1987). Also see 48 FR 25257, published on June 6, 1983; 52 FR 49189, published on December 30, 1987 and 53 FR 54, published on January 4, 1988.

James H. Babb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

August 9, 1988.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Mr. Commissioner: This directive amends, but does not cancel, the directive issued to you on May 27, 1983, as amended, by the Chairman, Committee for the Implementation of Textile Agreements. That directive, as amended on June 2, 1987, established export visa and exempt certification requirements for cotton, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Pakistan.

Effective on August 15, 1988, you are directed to permit entry of textile products visaed as merged Categories 226/313, 613/614, 638/639 and 647/648 which are exported from Pakistan on and after January 1, 1988.

Merged category quota merchandise may be accompanied by either the appropriate merged category visa or the correct category visa corresponding to the actual shipment (i.e., Categories 613/614 may be visaed as 613/614 or if the shipment consists solely of Category 613 merchandise, the shipment may be visaed as Category 613, but not Category 614).

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

James H. Babb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 88-18290 Filed 8-11-88; 8:45 am]

BILLING CODE 3510-DR-M

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

Procurement List 1988 Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Additions to procurement list.

SUMMARY: This list adds to Procurement List 1988 commodities, and a military resale commodity to be produced and services to be provided by workshops for the blind or other severely handicapped.

EFFECTIVE DATE: September 12, 1988.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202-3509.

FOR FURTHER INFORMATION CONTACT: E. R. Alley, Jr. (703) 557-1145.

SUPPLEMENTARY INFORMATION: On March 18, May 16, June 10, June 17, and June 24, 1988, the Committee for Purchase from the Blind and Other Severely Handicapped published notices (53 FR 8945, 17238, 21885, 22688, and 23783) of proposed additions to Procurement List 1988, December 10, 1987 (52 FR 46926).

After consideration of the relevant matter presented, the Committee has determined that the commodities, military resale commodity, and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51-2.6.

I certify that the following actions will not have a significant impact on a substantial number of small entities. The major factors considered were:

a. The actions will not result in any additional reporting, recordkeeping or other compliance requirements.

b. The actions will not have a serious economic impact on any contractors for the commodities, military resale commodity, and services listed.

c. The actions will result in authorizing small entities to produce the commodities, military resale commodity, and provide the services procured by the Government.

Accordingly, the following commodities, military resale commodity, and services is hereby added to Procurement List 1988:

Commodities

Pad, Writing Paper

7530-00-285-3090
(GSA Regions W, 2, 3, 4, 7, 8, 9 and 10)
7530-01-124-7632
(GSA Regions 4 and 6)

Pamphlets (3229-S)

7690-00-NSH-0010

(Requirements of Government Printing Office, Philadelphia, Pennsylvania—DLA Requisitions only)

Pad, Shoulder Strap

P.S. Item No. D-1212

Military Resale Item No. and Name

650 Dryer, Sweater

Services

Commissary Warehouse Service

Scott Air Force Base, Illinois

Janitorial/Custodial

Federal Building and U.S. Courthouse, 500 Fannin Street, Shreveport, Louisiana

Janitorial/Custodial

Building 1400, Hill Air Force Base, Utah

Janitorial/Custodial

Building 3504, Naval Amphibious Base, Little Creek, Norfolk, Virginia

Janitorial/Custodial and Grounds Maintenance

Naval Aviation Depot, Naval Air Station, Jacksonville, Florida.

E.R. Alley, Jr.,

Acting Executive Director.

[FR Doc. 88-18295 Filed 8-11-88; 8:45 am]

BILLING CODE 6820-33-M

Procurement List 1988 Addition

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Addition to procurement list.

SUMMARY: This action adds to Procurement List 1988 a commodity to be produced by workshops for the blind or other severely handicapped.

EFFECTIVE DATE: September 12, 1988.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202-3509.

FOR FURTHER INFORMATION CONTACT: E.R. Alley, Jr. (703) 557-1145.

SUPPLEMENTARY INFORMATION: On May 20, 1988, the Committee for Purchase from the Blind and Other Severely Handicapped published a notice (53 FR 18117) of proposed addition to Procurement List 1988, December 10, 1987 (52 FR 46926).

Comments were received from a law firm representing the International Association of Wiping Cloth Manufacturers (IAWCM) regarding the proposed addition of the Warner Robins, Georgia requirements for this wiping rag.

The major issues raised in the comments concerned the impact on the wiping rag industry, the Federal Government, and the environment if the Government's requirements for all wiping rags are added to the Procurement List. In addition, the commenter questioned the workshop's capability to meet surge demands by the Government and suggested the Committee should not use its procedures for determining the fair market price for the rags since the workshop has a free source for the raw materials.

Impact on Industry, Federal Government, and Environment

The commenter discussed the impact on the industry, Federal Government and the environment if the total requirements of the Federal Government for wiping cloths were to be added to the Procurement List. He indicated that the IAWCM members are gravely concerned that this action is only the first step in an attempt by the workshops to become the dominant or sole supplier of wiping rags to the Government.

The issue considered by the Committee is the addition of only the Warner Robins, Georgia requirements for the wiping rag, NSN 7920-00-205-1711 to the Procurement List. The statements made by the commenter regarding the effect on the wiping cloth industry, the Federal Government, and the environment if all of the Government's requirements for wiping rags were added to the Procurement List is not germane and is, therefore, inappropriate to be addressed by the Committee relative to this action.

The value of the current contractor's contract for the portion considered by the Committee in this action represents about 1.8% of the annual sales of that firm. This is not considered to be serious impact.

The Committee in its regulations (41 CFR 51-2.6 "Suitability") states that in deciding whether or not a proposed addition to the Procurement List would have a serious adverse impact on the current or most recent contractor, the Committee gives particular attention to the possible impact on that contractor's sales, including any cumulative impact as a result of other recent Committee actions.

Capability of Workshop to Produce

The commenter indicated that wiping cloths are considered by the Government to be "mission essential" and producers must be able to meet surge demands on an expedited basis. He questioned the workshop's capability to find appropriate personnel quickly due to the various operations involved in processing them for sale to the Government.

This addition will create three jobs for severely handicapped persons. If the Government's requirements were doubled, only three additional persons would be required. The Committee does not feel that the workshop will have difficulty in obtaining and training additional personnel to produce these wiping rags to meet the surge requirements of the Government. The procuring activity has indicated as a result of an on-site inspection that the workshop is capable of producing the wiping rags in compliance with commercial item description. In addition, personnel from the National Industries for the Severely Handicapped have inspected the workshop and verified that the workshop is capable of producing the wiping rags. Based on the above, the Committee has determined that the workshop is capable of producing the wiping rags in compliance with the Government's requirements.

Fair Market Price

The commenter stated that the Committee's fair market price procedure should not be used for these wiping rags since the workshop has a free source for raw materials.

Under the Committee's Act, the Committee is responsible for determining "fair market prices" for commodities and services on the Procurement List (41 U.S.C. 47(b)). The Committee considers that the reasonable bids received by the Government for the item under consideration are the best measure of the market for that item. Under its longstanding policy, the initial fair market prices for items being added to the Procurement List, which have been recently procured by the Government, are based on the median of the reasonable bids which were received on the most recent procurement, or the award price increased by 5%, whichever is greater. Thus, the workshop's cost for the raw materials used in producing the wiping rags for the Government is not an appropriate issue in the Committee determination of the fair market price for those rags.

Based on the preceding, the price established by the Committee is considered to be reflective of the market for the wiping rags and is a fair market price within the policies and procedures of the Committee.

After consideration of the relevant matter presented, the Committee has determined that the commodity listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51-2.6.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered were:

a. The action will not result in any additional reporting, recordkeeping or other compliance requirements.

b. The action will not have a serious economic impact on any contractors for the commodity listed.

c. The action will result in authorizing small entities to produce the commodity procured by the Government.

Accordingly, the following commodity is hereby added to Procurement List 1988:

Rag, Wiping

7920-00-205-1711
(Requirements for Warner Robins, Georgia only)

E.R. Alley, Jr.,

Acting Executive Director.

[FR Doc. 88-18296 Filed 8-11-88; 8:45 am]

BILLING CODE 6820-33-M

Procurement List 1988 Proposed Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed Additions to Procurement List.

SUMMARY: The Committee has received proposals to add to Procurement List 1988 a commodity to be produced and services to be provided by workshops for the blind and other severely handicapped.

COMMENTS MUST BE RECEIVED ON OR BEFORE: September 12, 1988.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202-3509.

FOR FURTHER INFORMATION CONTACT: E.R. Alley, Jr. (703) 557-1145.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51-2.6. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government will be required to procure the commodity and services listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodity and services to Procurement List 1988, December 10, 1987 (52 FR 46926).

Commodity

Side Rack, Vehicle
2510-00-860-0523

Services

Janitorial/Custodial
U.S. Post Office, Courthouse and Social Security Administration District Office, Hot Springs, Arkansas

Janitorial/Custodial
Domiciliary Buildings 8A, 10A, 14 A&B, 16 A&B, 25 and 34, VA Medical Center, Dublin, Georgia

Janitorial/Custodial
U.S. Courthouse Annex, 1100 East Main Street, Richmond, Virginia

E. R. Alley, Jr.

Acting Executive Director.

[FR Doc. 88-18297 Filed 8-11-88; 8:45 am]

BILLING CODE 6820-33-M

DEPARTMENT OF DEFENSE

Public Information Collection Requirement Submitted to OMB for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Applicable Form, and Applicable OMB Control Number: Description of Vessels/Description of Operations; ENG Forms 3931 and 3932; OMB Control Number 0702-0033.

Type of Request: Extension.

Average Burden Hours/Minutes Per Response: 60 minutes.

Frequency of Response: Annual.

Number of Respondents: 2,000.

Annual Burden Hours: 2,000.

Annual Responses: 2,000.

Needs and Uses: Statistical general use data is collected as required by 42 STAT 1043 on freight and passenger vessels operating in U.S. Waters, under the American flag. Transportation Lines of the United States (TLUS) contains information of the vessel operators and their American flag vessels operating or available for operation on the inland waterways of the United States in the transportation of freight and passengers.

Affected Public: Business or other for-profit.

Frequency: Annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Dr. Timothy Sprehe.

Written comments and recommendations on the proposed information collection should be sent to Dr. Timothy Sprehe at Office of Management and Budget, Desk Officer, Room 3235, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Ms. Pearl Rascoe-Harrison.

A copy of the information collection proposal may be obtained from, Ms. Rascoe-Harrison WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, Virginia 22202-4302, telephone (202) 746-0933.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

August 9, 1988.

[FR Doc. 88-18264 Filed 8-11-88; 8:45 am]

BILLING CODE 3810-01-M

Office of the Secretary

Department of Defense Wage Committee; Closed Meetings

Pursuant to the provisions of section 10 of Pub. L. 92-463, the Federal Advisory Committee Act, notice is hereby given that a meeting of the Department of Defense Wage Committee will be held on Tuesday, September 6, 1988; Tuesday, September 13, 1988; Tuesday, September 20, 1988; and Tuesday, September 27, 1988 at 10:00 a.m. in Room 1E801, The Pentagon, Washington, DC.

The Committee's primary responsibility is to consider and submit recommendations to the Assistant Secretary of Defense (Force Management and Personnel) concerning all matters involved in the development and authorization of wage schedules for federal prevailing rate employees pursuant to Public Law 92-392. At this meeting, the Committee will consider wage survey specifications, wage survey data, local wage survey committee reports and recommendations, and wage schedules derived therefrom.

Under the provisions of section 10(d) of Pub. L. 92-463, meetings may be closed to the public when they are "concerned with matters listed in 5 U.S.C. 552b." Two of the matters so listed are those "related solely to the internal personnel rules and practices of an agency," (5 U.S.C. 552b.(c)(2)), and those involving "trade secrets and commercial or financial information obtained from a person and privileged or confidential" (5 U.S.C. 552b.(c)(4)).

Accordingly, the Deputy Assistant Secretary of Defense (Civilian Personnel Policy) hereby determines that all portions of the meeting will be closed to the public because the matters considered are related to the internal rules and practices of the Department of Defense (5 U.S.C. 552b.(c)(2)), and the detailed wage data considered by the Committee during its meetings have

been obtained from officials of private establishments with a guarantee that the data will be held in confidence (5 U.S.C. 552b.(c)(4)).

However, members of the public who may wish to do so are invited to submit material in writing to the chairman concerning matters believed to be deserving of the Committee's attention.

Additional information concerning this meeting may be obtained by writing the Chairman, Department of Defense Wage Committee, Room 3D264, The Pentagon, Washington, DC 20301.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

August 9, 1988.

[FR Doc. 88-18265 Filed 8-11-88; 8:45 am]

BILLING CODE 3810-01-M

Defense Logistics Agency

Privacy Act of 1974; New Continuing Computer Matching Program Between Department of Defense and New York City Human Resources Administration

AGENCY: Defense Manpower Data Center (DMDC) of the Defense Logistics Agency (DLA), Department of Defense (DoD).

ACTION: Public notice of a Computer Matching Program between the DoD and the New York City Human Resources Administration for any public comment.

SUMMARY: The Department of Defense plans to participate in a computer matching program at the request of the New York City Human Resources Administration in it's efforts to detect fraud, waste and abuse in the public assistance programs administered by the City of New York. The computer match will compare the city's master file of public assistance clients with DoD records of active, retired, and reserve military members and DoD civilian employees, active and retired.

DATES: This proposed action shall be effective August 12, 1988. Nevertheless, any public comment will be considered provided comments are received on or before September 12, 1988.

ADDRESS: Comments may be submitted to Robert J. Brandewie, Deputy Director, Defense Manpower Data Center, 550 Camino El Estero, Suite 200, Monterey, CA 93940-3231. Telephone: (406) 375-4131.

FOR FURTHER INFORMATION CONTACT: Aurelio Nepa, Jr., Staff Director, Defense Privacy Office, Room 205, 400 Army Navy Drive, Arlington, VA 22202-2803. Telephone: (202) 694-3027.

SUPPLEMENTARY INFORMATION: The computer matching will be performed at the Defense Manpower Data Center (DMDC) in Monterey, CA. The DMDC, Defense Logistics Agency, Department of Defense, will be the matching agency and the New York City Human Resources Administration (NYC HRA) 250 Church Street, New York City, NY 10013, will be the benefitting source agency. The match will be accomplished using the social security number. The purpose of the match is to assist NYC HRA in it's efforts to identify individuals receiving public assistance, food stamps, medicaid or child support benefits from the City of New York to which they are not legally entitled to, or possibly a reduction in benefit entitlements may be in order. There will be some two million active individuals on this file representing active public assistance, food stamps, medicaid and child support. Matching records will be returned to NYC HRA who will be responsible for reviewing the match data and for assuring that each benefit recipient receives proper due process notification of the match results before any adverse action is taken to reduce or eliminate benefits.

Set forth below is the information required by the paragraph 5.f.(1) of the Revised Supplemental Guidance for Conducting Computerized Matching Programs, issued by the Office of Management and Budget on May 11, 1982 (47 FR 21656, May 19, 1982). A copy of this proposed notice has been provided to the President of the Senate, the Speaker of the House of Representatives and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget on July 27, 1988 pursuant to the cited OMB matching guidelines.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

August 9, 1988.

Report of a New Continuing Computer Matching Program Between the Department of Defense and the New York City Human Resources Administration

a. *Authority:* The legal authority under which the computer matching program will be conducted is subsection (b)(3) of the Privacy Act of 1974, 5 U.S.C. 552a; 7 U.S.C 2011-2029, Food Stamp Act of 1977, as amended; 10 U.S.C. 136, Assistant Secretaries of Defense; appointment; powers and duties; precedence; 7 CFR Part 273—Certification of Eligible Households (Agriculture); Title IV A (Public Assistance), Title IV D (Child Support), Title XVI (Medicaid) of the Social Security Act, 42 U.S.C 603, 651 through 658, 1302, 1382, 1902, Chapter IV, Subchapter C (Medical Assistance Programs); 45 CFR Part 206—Application, Determination of Eligibility and Furnishing Assistance—Public Assistance Programs (HHS); 45 CFR Chap III—Location of absent parents, actions to establish paternity and obtain and enforce support (Office of Child Support); 45 CFR Part 235—Administration of Financial Assistance Programs; Office of Management and Budget: "Revised Supplemental Guidance for Conducting Matching Programs," dated May 11, 1982 (47 FR 21656, May 19, 1982); New York State Rules and Regulations, Book 18—Social Services, Section 351-5.

b. *Program Description:* The matching program, established under a Memorandum of Understanding (MOU), will identify DoD employees and members who are recipients of New York City Human Resources Administration (NYC HRA) assistance benefits.

Upon receipt a computer tape file of all the active benefit accounts from NYC HRA, the Defense Manpower Data Center (DMDC) will perform a computer match using all nine digits of the social security numbers of the individuals concerned. All matching DoD records (hits) will be forwarded to NYC HRA along with the respective submission data consisting of the DoD employee or member's name, service (or agency), category of employee (active or retired), salary or retirement benefit, and current work or home address from DMDC's records. No information will be disclosed by DMDC from non-matching DoD records (non-hits).

The DMDC file for the match will utilize records of DoD active duty, retired and reserve military members and civilian personnel, both active and retired. DMDC, the matching agency, will be performing the computer match and NYC HRA will be the beneficial source agency furnishing a computer tape file on which to match containing some two million active individuals representing active public assistance, food stamps, medicaid and child support cases. Matching records (hits) will be furnished to NYC HRA who will be responsible for reviewing the matching data and assuring that individuals are positively identified as one and the same.

NYC HRA will utilize the hit data and make the initial follow-up determinations to close or reduce the benefits of NYC HRA benefit recipients who are not living in New York City or whose income exceed the allowable

standards. It may be used as a basis for determining continued eligibility and recouping benefit overpayments. It will also serve to identify, locate and report those individuals who may be able to provide child support to NYC HRA recipients to the Department of Child Support. NYC HRA will be responsible for assuring that the benefit recipient receives proper due process notification before any adverse action is taken on the part of NYC HRA. Any benefit recipient against whom a negative action is taken will be given the benefit of appeal.

DMDC will make reasonable efforts, pursuant to subsection (e)(6) of the Privacy Act (5 U.S.C. 55a), to assure that the DoD records are accurate, complete, timely, and relevant for agency purposes before disclosure. Further it will insure that an accounting of the disclosures are maintained pursuant to subsection (c) of the Privacy Act.

c. *Records to be Matched:* The DMDC, Defense Logistics Agency, system of records that is subject to the Privacy Act of 1974, and containing an appropriate routine use permitting the records contained therein to be used for this matching program, is identified as S322.10 DLA-LZ, entitled: "Defense Manpower Data Center Data Base." The notice for this record system was last published in the Federal Register at 53 FR 442 on February 16, 1988. The NYC HRA record system is entitled: "Extract of HR, AFDC, Food Stamps, Medicaid and missing parents file." This is not a Federal record system and is maintained by the New York City Human Resources Administration, Office of Systems Development, IM Programs, 354 Broadway—4th Floor, New York City, NY 10013.

d. *Period of the Match:* The initial match will commence after publication of this notice in the **Federal Register** and will be repeated periodically thereafter.

e. *Security Safeguards:* Automated records are accessible only by password and access to the computer centers is by key or picture identification. Hard copy records are maintained in Federal, State, City office buildings in lockable file cabinets and are accessed only by authorized Federal, State or City employees who have an official need to know.

f. *Retention and Disposition of Records:* Computer tapes received by DMDC will be returned to NYC HRA upon successful completion of each match and shall not be copied or used for any other purposes except as described above. The NYC HRA tape file will be used and accessed only to the matching agreed to; it will not be used to extract information concerning "non-hit" individuals for any purpsoe. Likewise, the DoD data provided to NYC HRA shall not be used for any other purpose other than described purposes above. Hard copy case file records created by NYC HRA as a result of the match will be used by the City of New York to determine continued benefit entitlement levels and to contact the benefit recipient if necessary. These individual case file records are within the exclusive control and jurisdiction of the City of New York.

[FR Doc. 88-18266 Filed 8-11-88; 8:45 am]

BILLING CODE 3810-01-M

Department of the Navy

Chief of Naval Operations Executive Panel Advisory Committee; Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given that the Chief of Naval Operations (CNO) Executive Panel Advisory Committee Latin America Task Force will meet August 30-31, 1988 from 9 a.m. to 5 p.m. each day, in Norfolk, Virginia. All sessions will be closed to the public.

The purpose of this meeting is to gain a broad overview and insight on Latin America related to U.S. security and naval interests. These matters constitute classified information that is specifically authorized by Executive order to be kept secret in the interest of national defense and is, in fact, properly classified pursuant to such Executive order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting, contact Faye Buckman, Secretary to the CNO Executive Panel Advisory Committee, 4401 Ford Avenue, Room 601, Alexandria, Virginia 22302-0268. Phone (703) 756-1205.

Date: August 8, 1988.

Jane M. Virga,

Lieutenant, JAGC, USNR, Alternate Federal Register Liaison Officer.

[FR Doc. 88-18246 Filed 8-11-88; 8:45 am]

BILLING CODE 3810-AE-M

Naval Research Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given that the Naval Research Advisory Committee Panel on Laser Weapons will meet on September 12-13, 1988. The meeting will be held at the Office of the Chief of Naval Research, Room 1020, 800 North Quincy Street, Arlington, VA. The meeting will commence at 9:00 a.m. and terminate at 5:00 p.m. on September 12; and will commence at 9:00 a.m. and terminate at 3:00 p.m. on September 13, 1988. All sessions of the meeting will be closed to the public.

The purpose of the meeting is to provide briefings for the panel members on laser weapons. The agenda will include discussions concerning the draft report and an intelligence update. These discussions and briefings will contain classified information that is specifically authorized under criteria established by Executive order to be kept secret in the interest of national defense and is in fact properly classified pursuant to such Executive order. The classified and nonclassified matters to be discussed are so inextricably intertwined as to preclude opening any portion of the meeting. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 522b(c)(1) of title 5, United States Code.

For further information concerning this meeting contact: Commander L.W. Snyder, U.S. Navy, Office of Naval Research, 800 North Quincy Street, Arlington, VA 22217-5000, Telephone Number: (202) 696-4879.

August 8, 1988.

Jane M. Virga,

Lieutenant, JAGC, U.S. Naval Reserve, Alternate Federal Register Liaison Officer.

[FR Doc. 88-18248 Filed 8-11-88; 8:45 am]

BILLING CODE 3810-AE-M

Naval Research Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given that the Naval Research Advisory Committee Panel on Countermine Capabilities for Amphibious Operations will meet on September 13-14, 1988. The meeting will be held at the Center for Naval Analyses, 4401 Ford Avenue, Alexandria, VA. The meeting will commence at 9:00 a.m. and terminate at 5:30 p.m. on September 13; and commence at 9:00 a.m. and terminate at 4:00 p.m. on September 14, 1988. All sessions of the meeting will be closed to the public.

The purpose of the meeting is to provide briefings for the panel members related to an assessment of the mine/

countermine threat and current capabilities and limitations, and an evaluation of the technological approaches to detection, neutralization, marking and reporting problems. The agenda will include discussions on amphibious warfare, mine warfare, countermine capabilities and limitations, and a threat assessment. These briefings and discussions will contain classified information that is specifically authorized under criteria established by Executive order to be kept secret in the interest of national defense and is in fact properly classified pursuant to such Executive order. The classified and nonclassified matters to be discussed are so inextricably intertwined as to preclude opening any portion of the meeting. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting contact: Commander L.W. Snyder, U.S. Navy, Office of Naval Research, 800 North Quincy Street, Arlington, VA 22217-5000, Telephone Number: (202) 696-4879.

Date: August 8, 1988.

Jane M. Virga,

Lieutenant, JAGC, U.S. Naval Reserve, Alternate Federal Register Liaison Officer.

[FR Doc. 88-18249 Filed 8-11-88; 8:45 am]

BILLING CODE 3810-AE-M

DEPARTMENT OF EDUCATION

Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Technology Services, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATE: Interested persons are invited to submit comments on or before September 12, 1988.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Jim Houser, Desk Officer, Department of Education, Office of Management and Budget, 726 Jackson Place NW., Room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Margaret B. Webster, Department of Education, 400 Maryland Avenue SW., Room 5624, Regional Office Building 3, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Margaret B. Webster, (202) 732-3915.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations.

The Director, Information Technology Services, publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Frequency of collection; (4) The affected public; (5) Reporting burden; and/or (6) Recordkeeping burden; and (7) Abstract. OMB invites public comment at the address specified above. Copies of the requests are available from Margaret Webster at the address specified above.

Dated: August 9, 1988.

Carlos U. Rice,

Director for Information Technology Services.

Office of Special Education and Rehabilitative Services

Type of Review: Reinstatement
Title: Report of Vending Facility Program
Frequency: Annually
Affected Public: State or local governments
Reporting Burden:
Responses: 51
Burden Hours: 423
Recordkeeping:
Recordkeepers: 0
Burden Hours: 0.
Abstract: State Vocational Rehabilitation agencies report on services to blind individuals under the Vending Facility Program. The Department will use the information to ensure financial accountability and solvency of the program.

Office of Postsecondary Education

Type of Review: Extension
Title: Request for Designation as an Eligible Institution
Frequency: Annually
Affected Public: Non-profit institutions
Reporting Burden:
Responses: 1,000
Burden Hours: 8,000
Recordkeeping:
Recordkeepers: 0
Burden Hours: 0.
Abstract: This form will be used by institutions of higher education to apply for funding under the Strenghtening Institutions Programs and the Endowment Challenge Grant Programs. The Department will use the information to make grant awards.

[FR Doc. 88-18281 Filed 8-11-88; 8:45 am]

BILLING CODE 4000-01-M

[84.116A]

Preapplications and Applications for New Awards Under the Comprehensive Program of the Fund for the Improvement of Postsecondary Education (FIPSE) for Fiscal Year 1988

Purpose: Provides grants to or enters into cooperative agreements with institutions of postsecondary education and other public and private institutions and agencies to improve postsecondary education and educational opportunities.

Deadline for Transmittal of Preapplications: October 18, 1988.

Deadline for Transmittal of Applications: March 1, 1989.

Application Available: August 26, 1988.

Estimated Size of Awards: $5,000 to $200,000 per year.

Estimated Number of Awards: 76.

Project Period: 12 to 36 months.

Available Funds

The President's Budget for fiscal year 1989 includes $13,500,000 for FIPSE. Of this amount, approximately $5,000,000 would be available for an estimated 76 new awards under the Comprehensive Program. The Congress has not yet completed action on the 1989 appropriation. The estimates above assume passage of the President's budget. These estimates, however, do not bind the Department of Education to a specific number of grants or to the amount of any grant.

Priorities

The Secretary supports a broad range of programs that seek to improve postsecondary education. In accordance with 34 CFR 75.105(c)(1), the Secretary invites applications addressing the

following priorities. However, the list is not meant to be exhaustive. Projects that do not meet any of these priorities are also eligible for support if they address other immediate problems or issues in postsecondary education.

Applications are invited that seek to:

(1) Ensure that undergraduate curricula provide the knowledge and skills which an educated citizen needs, including knowledge of our intellectual and cultural heritage;

(2) Ensure that recent increases in access to postsecondary education are made meaningful by improving retention and completion rates without compromising program standards;

(3) Improve the quality of undergraduate education by raising academic standards for the bachelors degree, strengthening the liberal arts component of undergraduate professional programs, developing means of assessing and comparing programs and institutions, and recognizing and rewarding outstanding undergraduate teaching through hiring, tenure, and promotion policies;

(4) Reform the education of school teachers by making it easier for able people to qualify as teachers who have earned degrees in fields other than education and who currently lack pedagogical training, increasing current and prospective teachers' mastery of the subjects they teach, ensuring that prospective teachers have a solid grounding in the liberal arts, and attracting more people of commitment and high intellectual ability to the teaching profession;

(5) Reform graduate education by fostering the teaching skills of Ph.D. candidates bound for careers in teaching, and broadening the social and ethical perspectives of students in professional graduate programs generally;

(6) Strengthen postsecondary educational institutions and organizations by providing incentives to develop the abilities of their leaders, administrators, faculty, and staff;

(7) Provide education for a changing economy by offering educational programs and services for workers, unemployed individuals, businesses, and communities;

(8) Develop educational uses of technology, including computers, television, and other electronic media.

Applicable Regulations

(a) The Education Department General Administrative Regulations, 34 CFR Parts 74, 75, 77, 78, and 80, (b) the regulations in 34 CFR Part 630, with the exception noted in 34 CFR 630.4.

For Applications and Information Contact: The Fund for the Improvement of Postsecondary Education, 400 Maryland Avenue, SW., Room 3100, ROB-3, Washington, DC 20202. Telephone (202) 732-5750 or 732-5766.

Program Authority: 20 U.S.C. 1135.

Dated: August 9, 1988.

Kenneth D. Whitehead,

Assistant Secretary for Postsecondary Education.

[FR Doc. 88-18364 Filed 8-11-88; 8:45 am]

BILLING CODE 4000-01-M

Office of Educational Research and Improvement

Advisory Council on Education Statistics; Meeting

AGENCY: Advisory Council on Education Statistics (ACES).

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Advisory Council on Education Statistics. This notice also describes the functions of the Council. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of their opportunity to attend.

DATES: September 15-16, 1988.

ADDRESS: 555 New Jersey Avenue NW., Room 326, Washington, DC 20208.

FOR FURTHER INFORMATION CONTACT: Iris Silverman, Executive Director, Advisory Council on Education Statistics, 555 New Jersey Avenue, Room 400J, Washington, DC 20208. Telephone: (202) 357-6831.

SUPPLEMENTARY INFORMATION: The Advisory Council on Education Statistics is established under section 406(c)(1) of the Education Amendments of 1974, Pub. L. 93-380. The Council is established to review general policies for the operation of the National Center for Education Statistics (NCES) in the Office of Educational Research and Improvement and is responsible for advising on standards to insure that statistics and analyses disseminated by NCES are of high quality and are not subject to political influence. The meeting of the Council is open to the public. The proposed agenda includes the following:.

- NCES: Two years After the National Academy of Sciences' Evaluation
- Report on the New Legislation
- Assessment of Student Learning in Postsecondary Education
- Update on the Dropout Program
- School Finance Program
- Council Business.

Records are kept of all Council proceedings and are available for public inspection at the Office of the Executive Director, Advisory Council on Education Statistics, 555 New Jersey Avenue NW., Room 400J, Washington, DC 20208.

Dated: August 4, 1988.

Chester E. Finn, Jr.,

Assistant Secretary for Educational Research and Improvement.

[FR Doc. 88-18272 Filed 8-11-88; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Intent to Award a Grant Agreement to International Building Performance Simulation Association (IBPSA)

AGENCY: U.S. Department of Energy (DOE).

ACTION: The U.S. DOE announces that pursuant to 10 CFR 600.7(b)(2), it is awarding a noncompetitive financial assistance instrument under grant number DE-FGO1-88CE21028 for a conference entitled "Building Simulation "89."

SUMMARY: The U.S. DOE, Office of Building and Community Systems (OBCS) is preparing a request to fund the proposed International Conference. The objectives of the conference are:

(a) To provide a forum for researchers, developers, and users of energy simulation models to come together and exchange ideas and information and encourage the advancement of knowledge; (b) to provide a forum for transferring information and technologies; (c) to foster excellence and professional growth in the field of building simulation; and (d) to publish and distribute the research papers presented at the conference on topics of special interest.

The conference will provide an interdisciplinary forum in which invited speakers will present the latest research results, advances in software development and integration, and other aspects of computerized simulation of building performance simulation, lighting simulation, acoustics simulation, thermal storage simulation, computer-aided design and knowledge-based design methods. It is anticipated that the symposium will attract contributions from architects and engineers, building managers, computer specialists and researchers, energy directors and researchers, DOE laboratories, and others interested in the use and

development of building simulation tools including officials from all levels of government.

The conference will provide DOE a timely opportunity to hear discussed the latest research and developments in the area of building simulation from foreign governments, determine how these developments compare to the developments under consideration by the United States, and determine whether the U.S. program should be modified to take advantage of new developments. The result will provide the basis for reviewing the merits of DOE's current research programs.

Eligibility

Award of this effort is restricted to IBPSA.

IBPSA has announced the conference, developed a planning document, established their agenda, established and made arrangements of the time and place, and obtained co-sponsorship from a variety of agencies. IBPSA's personnel are uniquely qualified to support such a conference.

The conference has been determined to be meritorious and relevant to the DOE mission. It is particularly relevant to the OBCS mission of leading a national effort to achieve the maximum, cost-effective energy productivity in the buildings sector. The term of this agreement will be six months.

FOR FURTHER INFORMATION CONTACT: Rosemarie H. Marshall, MA-153.2, U.S. Department of Energy, Office of Procurement Operations, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586-1061.

Thomas S. Keefe,

Director, Contract Operations Division "B", Office of Procurement Operations.

[FR Doc. 88-18308 Filed 8-11-88; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-3428-5]

Environmental Impact Statements and Regulations; Availability of EPA Comments Prepared July 25 Through 29, 1988

Availability of EPA comments prepared July 25, 1988 through July 29, 1988 pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 382-5074. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in **Federal Register** dated April 22, 1988 (53 FR 13318).

Draft EISs

ERP No. D-AFS-K61094-CA, Rating EO2, Sherwin Bowl Ski Area Development, Alpine Skiing, Special Use Permit, Inyo National Forest, Mammoth Ranger District, Mono County, CA. **SUMMARY:** EPA expressed environmental objections because the draft EIS did not analyze the cumulative environmental impacts of the ski areas planned for Inyo National Forest, and because impact analyses and mitigation plans for wetlands, water quality and air quality were inadequate.

ERP No. D-BLM-L67020-AK, Rating EO2, Fortymile River Watershed, Multiple Placer Mining Management Plan, Approval, Implementation and 404 Permit, Upper Yukon-Canada Subregion, AK. **SUMMARY:** EPA's concerns with this document relates to the lack of controls and mitigation incorporated into the proposed action and a range of alternatives and questions regarding the data necessary to provide the basis for conclusions which are presented.

ERA No. D-COE-K25005-CA, Rating EO2, Ox Mountain Sanitary Landfill Expansion, Apanolio Canyon Site, 404 Permit, Apanolio Creek, San Mateo County, CA. **SUMMARY:** EPA expressed environmental objections because the proposed project does not comply with the Clean Water Act section 404(b)(1) Guidelines, which regulates the discharge of dredged and fill material into waters of the United States, including wetlands. Specifically, this document did not provide enough information about alternative sites that may be less environmentally damaging; did not adequately analyze adverse impacts to wetlands, water quality and anadromous fisheries; and did not contain a mitigation plan that would be acceptable to fish and wildlife agencies.

ERP No. DS-COE-L36015-00, Rating EC1, Lower Granite Project, Lower Granite Interim Navigation and Flood Protection Dredging, Implementation, Snake and Clearwater Rivers, Nez Perce County, ID and Asotin, Garfield and Whitman Counties, WA. **SUMMARY:** EPA continues to be concerned with the potential adverse effects associated with the discharge of dredged material into aquatic habitats.

ERP No. D-DOE-J08023-ND, Rating LO, Charlie Creek-Belfield 345 kV Transmission Line Project, Construction, Operation and Maintenance, Implementation, Billings, Stark, McKenzie and Dunn Counties, ND. **SUMMARY:** EPA has not identified any potential environmental impacts requiring substantive changes to the draft proposal. However, it was pointed out that additional information on mitigation of impacts to wetlands would improve the documents.

ERP No. D-FHW-D40234-MD, Rating **2, I-695/Baltimore Beltway, US 40 West to MD-170 and MD-295/ Baltimore-Washington Expressway, MD-46 to the Baltimore City Line Improvements, Funding and 404 Permit, Baltimore and Anne Arundel Counties, MD. **SUMMARY:** EPA has reviewed this document for I-695 from U.S. 40 (west) to MD 170, including MD 295 from MD 46 to the Baltimore City Line. Alternate 1 (No Build), Alternate 2 (Mainline Widening), Interchange Option 1 and Interchange Option 2 were rated EC-2. This rating is based upon potential adverse noise impacts to residential communities. Interchange Option 3, however, has been given a separate rating of EO-2. This rating reflects EPA's concern regarding potential impacts to parkland and wetlands resulting from I-695/Maryland Route 295 Interchange Option 3.

ERP No. D-FRC-D05122-00, Rating EO2, Upper Ohio River Basin Hydroelectric Development, Construction, Operation and Maintenance, Licenses, Belmont, Gallia, Jefferson, Mahoning and Washington Cos., OH; Hancock Co., WV and Butler, Beaver, Allegheny, Armstrong, Fayette, Washington and Westmoreland Cos., PA. **SUMMARY:** EPA expressed concerns over entrainment of fish dissolved oxygen in the water, and pressure of toxics in the water.

ERP No. DA-UMT-K54014-CA, Rating LO, Los Angeles Rail Rapid Transit Project, Sunset Boulevard Alternate Alignment, Updated Project Cost, Impacts on MacArthur Park, Vermont Avenue/Sunset Boulevard Station Location and Cumulative Impacts of the Hollywood Bowl Connector, Funding, Los Angeles County, CA. **SUMMARY:** EPA expressed a lack of objections to the proposed action and supplemental draft EIS.

Final EISs

ERP No. F2-BLM-K65040-CA, Eastern San Diego County Planning Unit, Section 202 WSA's, Wilderness Recommendations, Designation or Nondesignation, San Ysidro Mountain, Sawtooth Mountains, A, Sawtooth Mountains C and Table Mountain, WSAs, El Centro Resource Area, California Desert District, San Diego County, CA. **SUMMARY:** Review of this document was not deemed necessary.

No formal comments were sent to the agency.

ERP No. F-FHW-D40214-PA, PA-23/New Holland Avenue/LR-1124, Section B01 Relocation, US 30 to Walnut and Chestnut Streets, Funding and 404 Permit, Manheim, East Lampeter and Lancaster Townships and the City of Lancaster, Lancaster County, PA. **SUMMARY:** EPA's concerns were satisfactorily addressed in this document.

Regulations

ERP No. R-OSH-A27010-00, 29 CFR Part 1910—Air Contaminants, Proposed Rule (OSHA Docket No. H-020) (53 FR 20960). **SUMMARY:** While stating that the proposed rule changes represent a substantial and desirable effort, EPA believes that some recent critical studies were not discussed. These studies were provided.

Amended Notices

The following is a correction to the summary published in the 8-5-88 FR Notice.

ERP No. D-SCS-H36100-MO, Rating LO, East Yellow Creek Watershed, Soil Erosion and Flood Damage Reduction Plan, Funding and Implementation, Sullivan, Linn and Chariton Counties, MO. **SUMMARY:** EPA has no objections to the project as proposed.

Dated: August 9, 1988.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 88-18315 Filed 8-11-88; 8:45 am]

BILLING CODE 6560-50-M

[ER-FRL-3428-4]

Environmental Impact Statements; Availability of Environmental Impact Statements Filed August 1, 1988 Through 5, 1988

Responsible Agency: Office of Federal Activities, General Information (202) 382-5076 or (202) 382-5075.

EIS No. 880246, FSuppl, AFS, OR, WA, ID, CA, Pacific Northwestern Regional Guide, Northern Spotted Owl Habitat Management Standards and Guidelines, Updated and Additional Research, OR, WA and CA, Due: September 12, 1988, Contact: Larry Fellows (503) 221-4923.

EIS No. 880247, DSuppl, AFS, MT, 1987 Deerlodge National Forest, Noxious Weed Control Program, Herbicide Use, Implementation, Deer Lodge, Granite, Jefferson, Madison, Powell and Silver Bow Counties, MT, Due: October 14, 1988, Contact: Dave Ruppert (406) 496-3368.

EIS No. 880248, FSuppl, EPA, OH, Columbus Metropolitan Area, Wastewater Treatment Facilities, Construction Grant, Franklin, Delaware, Fairfield, Madison and Pickaway Cos., OH, Due: September 12, 1988, Contact: Harlan D. Hirt (312) 353-2315.

EIS No. 880249, FSuppl, EPA, MA, Boston Metropolitan Area WWT/Disposal Facilities Expansion, Construction Grant, Boston Harbor, Suffolk County, MA, Due: September 12, 1988, Contact: David Tomey (617) 565-4420.

EIS No. 880250, Draft, COE, CA, Shell Hercules Project, Oil and Gas Resources Development, Section 10 and 404 Permits, Santa Barbara Channel, Santa Barbara County, CA, Due: October 4, 1988, Contact: David Cranston (213) 894-0245.

Amended Notices

EIS No. 880221, Draft, FAA, MD, 15L/33R Runway Extension, Baltimore/Washington International Airport, Approval and Funding, Anne Arundel County, MD, Due: August 31, 1988, Contact: Frank Squeglia (718) 917-0902.

Published **Federal Register** July 15, 1988—Review period extended.

Dated: August 9, 1988.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 88-18314 Filed 8-11-88; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

Applications for Consolidated Hearing; Boyd Enterprises, Inc., and George S. Flinn, Jr.

1. The Commission has before it the following mutually exclusive applications for a new FM station.

Applicant, city and State	File No.	MM Docket No.
A. Boyd Enterprises, Inc.; Humboldt, Tn.	BPH-870504MA	88-353
B. George S. Flinn, Jr.; Humboldt, TN.	BPH-870506KE	

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirely under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

Issue Heading and Applicant(s)

1. Environment, A
2. Air Hazard, B
3. Comparative, All
4. Ultimate, All

3. If there is any non-standardized issue(s) in this proceeding, the full text of the issue and the applicant(s) to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street, NW., Washington, DC 20037. (Telephone (202) 857-3800).

W. Jan Gay,

Assistant Chief, Audio Services Division, Mass Media Bureau.

[FR Doc. 88-18273 Filed 8-11-88; 8:45 am]

BILLING CODE 6712-01-M

Applications for Consolidated Hearing; Lawrence L. Bush, Jr. et al.

1. The Commisstion has before it the following mutually exclusive applications for a new FM station:

Applicant, city and state	File No.	MM Docket No.
A. Lawrence L. Bush, Jr.; Clifton, TX.	BPH-870325KC	88-359
B. Spanish Aural Services Co.; Clifton, TX.	BPH-870331MY	.....
C. Robert W. Prikryl and John R. Hanna, d/b/a Prikyl-Hanna Parternership; Clifton, TX.	BPH-870331OF	.....
D. Smith Media, Inc.; Clifton, TX.	BPH-870331OI	.....
E. Clifton Communications; Clifton, TX.	BPH-870331MU (Previously Dismissed)	.....

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347 (May 29, 1986). The letter shown before each applicant's name, above, is used below to signify

whether the issue in question applies to that particular applicant.

Issue heading and applicants

1. Air Hazard, B
2. Comparative, A–D
3. Ultimate, A–D

3. If there are any non-standard issues in this proceeding, the full text of the issue and the applicants to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street NW., Washington, DC 20037. (Telephone (202) 857–3800).

W. Jan Gay,

Assistant Chief, Audio Services Division, Mass Media Bureau.

[FR Doc. 18274 Filed: 8–11–88; 8:45 a.m.]

BILLING CODE 6712-01-M

Applicants for Consolidated Hearing; Larry Langford, et al.

1. The Commission has before it the following mutually exclusive applications for a new FM station:

Applicant, city and State	File No.	Docket No.
A. Larry Langford; Portage, MI.	BPH-851022MO	88-346
B. PN Radio Co.; Portage, MI.	BPH-851113MF	.....
C. Horizon Broadcasting Co.; Portage, MI.	BPH-851114MH	.....
D. Radio Associates Inc.; Portage, MI.	BPH-851114MI	.....
E. Walker-Kent Broadcasting Co.; Portage, MI.	BPH-851115MP	.....
F. Steven J. Kuiper; Portage, MI.	BPH-851115MQ	.....
G. William Bryant d/b/a Portage FM Group; Portage, MI.	BPH-851115MR	.....
H. WHW Broadcasting Group, Limited Partnership; Portage, MI.	BPH-851115MS	.....
I. Portage Communications, Inc.; Portage, MI.	BPH-851115MU	.....

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347 (May 29, 1986). The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

Issue heading and applicant

1. Air Hazard, E, G
2. Comparative, All
3. Ultimate, All

3. If there are any non-standardized issue in this proceeding, the full text of the issue and the applicant to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street NW., Washington, DC 20037. (Telephone (202) 857–3800).

W. Jan Gay,

Assistant Chief, Audio Services Division, Mass Media Bureau.

[FR Doc. 18275 Filed: 8–11–88; 8:45 am]

BILLING CODE 6712-01-M

Applications for Consolidated Hearing; Swan Broadcasting, Ltd., et al.

1. The Commission has before it the following mutually exclusive applications for a new TV station.

Applicant and city/State	File No.	MM Docket No.
A. Swan Broadcasting, Ltd.; New Oreleans, LA.	BPCT-870717KQ	88-357
B. Crescent City Broadcasting Corp.; New Orleans, LA.	BPCT-880419KE	.....
C. Delta Broadcasting of Louisiana, Ltd.; New Orleans, LA.	BPCT-880419KF	.....
D. Tucker Broadcasting Co., Ltd. Partnership; New Orleans, LA.	BPCT-880419KG	
E. Tracy Lewis, Ltd. Partnership; New Orleans, LA.	BPCT-880419KH	
F. Cajun Broadcasting; New Orleans, LA.	BPCT-880419KI	

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

Issue Heading and Applicant(s)

Comparative, A, B, C, D, E, F
Ultimate, A, B, C, D, E, F

3. If there is any non-standardized issue(s) in this proceeing, the full test of the issue and the applicant(s) to which it applies are set forth in the Appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street, NW., Washington, DC 20037 (Telephone No. (202) 857–3800).

Roy J. Stewart,

Chief, Video Services Division, Mass Media Bureau.

[FR Doc. 88–18276 Filed 8–11–88; 8:45 am]

BILLING CODE 6712-01-M

Applications for Consolidated Proceeding; Texas Communications Limited Partnership, et al.

1. The Commission has before it the following mutually exclusive applications for a new FM station:

Applicant, city and State	File No.	MM Docket No.
A. Texas Communications Limited Partnership; Beaumont, TX.	BPH-870710MJ	88-358
B. Juan Jose Gonzales; Beaumont, TX.	BPH-870710MW	
C. Beaumont Skywave, Inc.; Beaumont, TX.	BPH-870710NA	
D. CHM Broadcasting; Beaumont, TX.	BPH-870710NC	

Applicant, city and State	File No.	MM Docket No.
E. Beaumont Radio Limited Partnership; Beaumont, TX.	BPH-870710NR	
F. P.K.L. Partnership; Beaumont, TX.	BPH-870709ME (Previously dismissed)	

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particualr applicant.

Isue Heading and Applicant(s)

1. Environmental, C
2. Air Hazard, A,B,D,E
3. Comparative, All
4. Ultimate, All

3. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street, NW., Washington, D.C. 20037 (Telephone No. (202) 857-3800).

W. Jan Gay,

Assistant Chief, Audio Services Division, Mass Media Bureau.

[FR Doc. 88-18277 Filed 8-11-88; 8:45 am]

BILLING CODE 6712-01-M

Applications for Consolidated Hearing; WCVQ, Inc., et al.

1. The Commission has before it the following mutually exclusive applications for a new TV station:

Applicant, city and State	File No.	MM Docket No.
A. WCVQ, Inc.; Burlington, VT.	BPCT-871224KG	88-352
B. Nichols Broadcasting Corp.; Burlington, VT.	BPCT-880301KF	.....
C. Maple Leaf Broadcasting Limited Partnership; Burlington, VT.	BPCT-880301KG	.....
D. Lake Champlain Communications, Inc.; Burlington, VT.	BPCT-880301KH	.....
E. Burlington Channel 44, Inc.; Burlington, VT.	BPCT-880301KI	.....
F. Northeast Kingdom TV, Inc.; Burlington, VT.	BPCT-880301KJ	.....
G. Burlington 44 Co; Burlington, VT.	BPCT-880301KL	.....
H. David McMeekin; Burlington, VT.	BPCT-880301KM	.....

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

Issue Heading and Applicant(s)

1. Air Hazard, A,B,C,D,E,F,G,H
2. Comparative, A,B,C,D,E,F,G,H
3. Ultimate, A,B,C,D,E,F,G,H

3. If there is any non-standardized issue(s) in this proceeding, the full text of the issue and the applicant(s) to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street, NW., Washington, DC 20037 (Telephone No. (202) 857-3800).

Roy J. Stewart,

Chief, Video Services Division, Mass Media Bureau.

[FR Doc. 88-18278 Filed 8-11-88; 8:45 am]

BILLING CODE 6712-01-M

Applications for Consolidated Proceeding; Whiteaker Communications et al.

1. The Commission has before it the following mutually exclusive applications for a new FM station:

Applicant, city, and State	File No.	MM Docket No.
A. Whiteaker Communications; Crossville, TN.	BPH-860812MA	88-354
B. Mark A. Perry; Crossville, TN.	BPH-860813MW	
C. Audio Broadcasters, Inc.; Crossville, TN.	BPH-860813MX	

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applicants have been designated for a hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used to signify whether the issue in question applies to that particular applicant.

Issue Heading and Applicants

1. Air Hazard, B
2. Comparative, A, B, C
3. Ultimate, A, B, C

3. If there is any non-standardized issue in this proceeding, the full text of the issue and the applicants to which it applies are set forth in the Appendix to this Notice. A copy of the complete HDO in this proceeding is available in the FCC Dockets branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street, NW., Washington, DC 20037 (Telephone No. (202) 857-3800).

W. Jan Gay,

Assistant Chief, Audio Services Division, Mass Media Bureau.

[FR Doc. 88-18279 Filed 8-11-88; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL RESERVE SYSTEM

Credit and Commerce American Holdings, N.V., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications

are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. 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.

Unless otherwise noted, comments regarding each of these applications must be received not later than September 2, 1988.

A. **Federal Reserve Bank of Richmond** (Lloyd W. Bostian, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *Credit and Commerce American Holdings, N.V.*, Curaco, Netherlands Antilles; Credit and Commerce American Investment, N.V., Amsterdam, Netherlands; First American Corporation, Washington, DC; First American Bankshares, Inc., Washington, DC; Georgia Bankshares, Inc., Atlanta, Georgia; and National Bank of Georgia Corporation, Atlanta, Georgia; to acquire 100 percent of the voting shares of Bank of Escambia, N.A., Pensacola, Florida.

B. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Alabama Bancorp*, Leeds, Alabama; to acquire 50.2 percent of the voting shares of Highland Bank, Birmingham, Alabama, a *de novo* bank.

C. **Federal Reserve Bank of Chicago** (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Valley Banc Services Corp.*, St. Charles, Illinois; to acquire 100 percent of the voting shares of V.B.H. Corporation, Viola, Illinois, and thereby indirectly acquire Bank of Viola, Viola, Illinois.

D. **Federal Reserve Bank of Dallas** (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Ford Bank Group, Inc.*, Lubbock, Texas; to acquire 100 percent of the voting shares of Lubbock Bancorporation, Inc., Lubbock, Texas, and thereby indirectly acquire Bank of the West, Lubbock, Texas.

Board of Governors of the Federal Reserve System, August 8, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-18239 Filed 8-11-88; 8:45 am]

BILLING CODE 6210-01-M

Equimark Corp.; Correction

This notice corrects a previous **Federal Register** notice (FR Doc. 88-15424) published at page 26116 of the issue for Monday, July 11, 1988.

Under the Federal Reserve Bank of Cleveland, the first entry, for Equimark Corporation, is revised to include the following individual as an acquiring party:

Stephen A. Harrison, Pittsburgh, Pennsylvania.

Comments on this application must be received by August 26, 1988.

Board of Governors of the Federal Reserve System, August 5, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-18238 Filed 8-11-88; 8:45 am]

BILLING CODE 6210-01-M

National Community Banks, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. 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.

Unless otherwise noted, comments regarding each of these applications must be received not later than September 2, 1988.

A. **Federal Reserve Bank of New York** (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *National Community Banks, Inc.*, Maywood, New Jersey; to become a bank holding company by acquiring 100 percent of the voting shares of National Community Bank of New Jersey, Rutherford, New Jersey.

B. **Federal Reserve Bank of Cleveland** (John J. Wixted. Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *First National Cincinnati Corporation*, Cincinnati, Ohio; to acquire 100 percent of the voting shares of Star Bank, National Association, Cleveland, Cleveland, Ohio, a *de novo* bank.

2. *Hometown Bancshares, Inc.*, Middlebourne, West Virginia; to acquire 100 percent of the voting shares of The Community Bank of Pennsboro, Pennsboro, West Virginia.

3. *Hometown Bancshares, Inc.*, Middlebourne, West Virginia; to become a bank holding company by acquiring 100 percent of the voting shares of Union Bank of Tyler County, Middlebourne, West Viriginia.

C. **Federal Reserve Bank of Chicago** (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Western Springs Bancorp, Inc.*, Chicago, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of Continental Illinois Bank of Western Springs, National Association, Western Springs, Illinois.

Board of Governors of the Federal Reserve System, August 5, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-18240 Filed 8-11-88; 8:45 am]

BILLING CODE 6210-01-M

Jack Stern; Change in Bank Control Notice; Acquisition of Shares of Banks or Bank Holding Companies

The notificant listed below has applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and §225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the

Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 26, 1988.

A. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Jack Stern,* Denver, Colorado; to acquire 4.42 percent of the voting shares of Equitable Bankshares of Colorado, Inc., Denver, Colorado, and thereby indirectly acquire The Women's Bank, N.A., Denver, Colorado.

Board of Governors of the Federal Reserve System, August 5, 1988

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-18241 Filed 8-11-88; 8:45 am]

BILLING CODE 6210-01-M

United Bankshares, Inc., et al.; Notice of Application to Engage de Novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo,* either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for banking holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing 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.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 2, 1988.

A. **Federal Reserve Bank of Richmond** (Lloyd W. Bostian, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *United Bankshares, Inc.,* Charleston, West Virginia; to engage *de novo* through its subsidiary, United Venture Fund, Inc., Parkersburg, West Virginia, in making and servicing commercial loans and other extensions of credit and making equity investments of 5 percent or less pursuant to § 225.25(b)(1)(iv) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, August 8, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-18242 Filed 8-11-88; 8:45 am]

BILLING CODE 6210-01-M

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period:

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 072588 AND 080588

Name of Acquiring person, Name of Acquired person, Name of Acquired entity,	PMN No.	Date terminated
The Prospect Group, Inc, Best Products Co., Inc., Best Products Co., Inc	88-1950	07/25/88
R.T. Holding S.A., William C. Metz, Metz Baking Company	88-1957	07/25/88
Swire Pacific Ltd., Inland Coca-Cola Bottling Company, Inland Coca-Cola Bottling Company	88-1988	07/25/88
General Motors Corporation, Bennett S. LeBow (LeBow Industries Inc.), Western Union Corporation	88-1990	07/25/88
Steelcase Inc., Ralph Saltzman, Design Tex Fabrics, Inc. & Western States Design, Inc	88-2004	07/25/88
Masco Industries, Inc., PCI Acquisition Corp., PCI Acquisition Corp	88-2039	07/25/88
Masco Corporation, PCI Acquisition Corp., PCI Acquisition Corp	88-2041	07/25/88
Broad Street Investment Fund I, L. P., PCI Acquisition Corp., PCI Acquisition Corp	88-2042	07/25/88
Mr. and Mrs. Bruce G. Meltzer, U.S. Home Corporation, Dee Wood Industries, Inc	88-2069	07/25/88
Trust America Service Corp., The Equitable Life Assurance Society of the U.S., Equitable Mortgage Resources Inc	88-2072	07/25/88
The Henley Group, Inc., The Pullman Company, The Pullman Company	88-2076	07/25/88
Thomas F. Darden, II and Josephine R. Darden, JWC Associates L.P., c/o Kohlberg Kravis Roberts & Co. of North Carolina, Sanford Brick Corp	88-2079	07/26/88
Royal Dutch Petroleum Company, GORCO N.V., Guam Oil & Refining Company, Inc	88-1972	07/27/88
American Information Technologies Corporation, Pacific Telesis Group, Multicom Incorporated	88-2052	07/27/88
Tele-Communications, Inc., Tele-Communications, Inc., St. Louis Cablevision Partners	88-2061	07/27/88
Tele-Communications, Inc., William T. Johnson, St. Louis City Communications, Inc	88-2066	07/27/88
American Capital and Research Corporation, Kaiser Engineers Groups, Inc., Kaiser Engineers Group, Inc	88-2081	07/27/88
American Capital and Research Corporation, Kaiser Engineers Group, Inc., Kaiser Engineers Group, Inc	88-2082	07/27/88
Steven Adams, Ralph Ingersoll, Orange Coast Publishing Company	88-1934	07/28/88

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 072588 AND 080588—Continued

Name of Acquiring person, Name of Acquired person, Name of Acquired entity,	PMN No.	Date terminated
Steven Adams, Warburg, Pincus Capital Partners, L.P., Orange Coast Publishing Company	88-1935	07/28/88
Michael George DeGroote, John L. May Archbishop of St. Louis, West Lake Landfill, Inc	88-1996	07/28/88
Koninklijke Wessanen N.V., Arthur Stone, Gourmet Foods, Inc	88-2009	07/28/88
Ryobi Limited, Bilzerian Partners Limited Partnership 1, The Singer Company (Motor Products Division)	88-2051	07/28/88
The Oklahoma Publishing Company, El Pomar Foundation, Broadmoor Hotel, Inc	88-2106	07/28/88
Kenneth M. Good, D. Dudley Field, Mortgage First Corporation	88-2173	07/28/88
Kenneth M. Good, D. Porter Spangler, Mortgage First Corporation	88-2174	07/28/88
D. Max Draime, Maverick Management Partnership, ST Acquisition Corporation	88-2035	07/29/88
Arabian Investment Banking Corporation (INVESTCORP) EC, Fred Harvey, Jr., The Harvey Co	88-2046	07/29/88
Air Products and Chemicals, Inc., United Merchants and Manufacturers, Inc., Valchem Division	88-2063	07/29/88
PaineWebber Income Properties Eight Limited Partnership, Marriott Coroporation, Essex House Condominium Corporation	88-2092	07/29/88
Leonard Tow, Don A. Adam, Yuma Cablevision and Imperial Valley Cablevision	88-2094	07/29/88
Allegiance Capital Corporation, American Bankers Insurance Group, Inc., Financial Insurance Group Limited	88-2095	07/29/88
William Collins PLC, The Zondervan Corporation, The Zondervan Corporation	88-2098	07/29/88
The News Corporation Limited, The Zondervan Corporation, The Zondervan Corporation	88-2099	07/29/88
Airlease Ltd., a California Limited Partnership, Douglas Wolf, DC-9T-II, Inc. and DC-9T-III, Inc	88-2107	07/29/88
Ford Motor Company, Douglas Wolf, DC-9T-II, Inc. and DC-9T-III, Inc	88-2110	07/29/88
The B.F. Goodrich Company, Ronald D. Crockett, TRAMCO, Inc. and R & B Sales, Inc	88-2115	07/29/88
The B.F. Goodrich Company, Robert M. and Kathleen B. Trimble, husband and wife, TRAMCO, Inc. and R & B Sales, Inc	88-2116	07/29/88
William Colins PLC, The Zondervan Corporation, The Zondervan Corporation	88-2121	07/29/88
The News Corporation Limited, The Zondervan Corporation, The Zondervan Corporation	88-2122	07/29/88
Standard Federal Savings Bank, Firstbank of Illinois Co., Firstbank Mortgae Co	88-2125	07/29/88
Baker Hughes Incorporated, Baker Hughes Incorporated, BJ-Titan Services, a partnership	88-2138	07/29/88
Gulf + Western Inc., International Controls Corp., Great Dane Finance Company	88-2139	07/29/88
The Rank Organization Plc, Lieberman Enterprises Incorporated, International Video Entertainment Inc	88-2087	08/01/88
Robert M. Bass, MacAcq Holdings Corp., MacAcq Holdings Corp	88-2103	08/01/88
Arcadia Partners, L.P., MacAcq Holdings Corp., MacAcq Holdings Corp	88-2104	08/01/88
M Texas TW Partners Ltd., MacAcq Holdings Corp., MacAcq Holdings Corp	88-2105	08/01/88
Thorn Apple Valley, Inc., Max A. Miller, Ivan Miller Family Limited Partnership, Tri-Miller Packing Company, Miller's Transport	88-2054	08/02/88
Vishay Intertechnology, Inc., Sfernice S.A., Sfernice S.A	88-2086	08/02/88
Compagnie Financiere Sucres et Denrees, Empress International, Ltd., Empress International, Ltd	88-2088	08/02/88
Stephen Adams, Price Communications Corporation, Old North Broadcasting Corporation	88-2109	08/02/88
Waste Management, Inc., The Brand Companies, Inc., The Brand Companies, Inc	88-1969	08/03/88
Brierley Investments Limited, Durham Corporation, Durham Corporation	88-2023	08/03/88
H.F. Lenfest, Time Incorporated, Time Incorporated	88-2074	08/03/88
Time Incorporated, H.F. Lenfest, H.F. Lenfest	88-2075	08/03/88
The Peninsular and Oriental Steam Navigation Company, The Vlasov Trust, Sitmar International, Inc	88-2136	08/03/88
Carey Salt Acquisition Company, Canadian Pacific Limited, Carey Salt, Inc	88-2089	08/04/88
Carlton Communications Plc, Ronald O. Perelman, Technicolor Holdings, Inc	88-2097	08/04/88
Time Incorporated, Memphis CATV, Inc., Memphis CATV, Inc	88-2102	08/04/88
Myron Kunin (Regis Corp.), Goldome, S&L Acquisition Company, L.P., Seligman & Latz of PR Inc	88-2128	08/04/88
The Pillsbury Company, Bumble Bee Seafoods, Inc., Bumble Bee Seafoods, Inc	88-2146	08/04/88
W.D. Company, Inc., Maverick Management Partnership, Joseph Horne Co., Inc	88-2030	08/05/88
Sequa Corporation, PepsiCo, Inc., Allegheny Bottling Company and Pepsi-Cola Bottling Co	88-2053	08/05/88
Noranda, Inc., Generale Occidentale, Certain timberlands of GO	88-2108	08/05/88
Hasbro, Inc., Coleco Industries, Inc., Coleco Industries, Inc	88-2111	08/05/88
George A. Mee, Societe Nationale Elf Acquitaine, Tg Forest Products, Inc	88-2151	08/05/88
Robert Harvey, c/o McGuire-Nicholas Company, Vision Hardware Group, Inc., Vision Hardware Group, Inc	88-2156	08/05/88
Nelson Peltz (Triangle Industries, Inc.), Samuel A. Horvitz Testamentary Trust, Samuel A. Horvitz Testamentary Trust	88-2166	08/05/88
Peter W. May (Triangle Industries, Inc.), Samuel A. Horvitz Testamentary Trust, Samuel A. Horvitz Testamentary Trust	88-2167	08/05/88
Marriott Corporation, Walgreen Co., Walgreen Co	88-2177	08/05/88
Cloud L. Cray, Jr., Midwest Grain Products, Inc., Midwest Grain Products, Inc	88-2189	08/05/88
Russell M. Jedinak, Frank J. Mola, FJM	88-2225	08/05/88

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative, Premerger Notification Office, Bureau of Competition, Room 301, Federal Trade Commission, Washington, DC 20580, (202) 326-3100.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 88-18236 Filed 8-11-88; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Department of Health and Human Services (HHS) publishes a

list of information collection packages it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on August 5, 1988.

Public Health Service

(Call Reports Clearance Officer on 202-245-2100 for copies of package)

Food and Drug Administration

1. Medical Device Standards Activities Report—0910-0219—The Medical Device Standards Activities Report is a comprehensive listing of national and international standards activities. It serves as a basis for the continuing review of existing standards for class II devices and as a guideline for the development of new standards. The report is used by government agencies, hospitals, libraries, industry, small businesses, and private citizens to keep abreast of the development of standards for medical devices. Respondents: Business or other for-profit, Federal agencies or employees, Non-profit institutions, Small business or organizations. Number of Respondents: 37; Frequency of Response: Bi-annually; Estimated Annual Burden: 67 hours.

Social Security Administration

(Call Reports Clearance Officer on 301-965-4149) for copies of package)

Office of Disability

1. Application for Benefits Under The Federal Mine Safety and Health Act of 1977—0960-0118—The information is needed to identify the deceased miner and to establish the relationship of the claimant for survivors benefits. Respondents: Individuals or households. Number of Respondents: 2,700; Frequency of Respone: 1; Estimated Annual Burden: 495 hours.

2. Medical Report (Individual with Childhood Impairment)—0960-0102—This form is used to collect information to determine if an individual with a childhood impairment is entitled to disability benefits. Respondents: Individuals or households; Number of Response: 75,000; Frequency of Response: 1; Estimated Annual Burden: 37,500 hours.

OMB Desk Officer: Shannah Koss-McCallum.

Center for Disease Control

1. Regulation 42 CFR 84, (NPRM)—Respiratory Protection Devices Tests for Permissibility—New—Advances in technology during the past 15 years created a need for revision in tests and requirements for certification of industrial respiratory protective devices. This clearance request places primary responsibility for certification with NIOSH and preserves a consultative role for MSHA in approval of emergency respirators. Manufacturers submit to NIOSH respirator design documentation and applications for approval. In final form, this NPRM replaces 30 CFR 11. Respondents: Business or other for-profit, Small business or organizations. Number of Respondents: 1; Frequency of Response: On occasion; Estimated Annual Burden: 1.

OMB Desk Officer: Shannah Koss-McCallum.

Health Care Financing Administration

(Call Reports Clearance Officer on 301-966-2088 for copies of package)

1. Hospice Survey Report Form—0938-0379—This survey form is an instrument used by the State agency to record data collected in order to determine provider compliance with individual conditions of participation and to report it to the Federal government. Respondents: State or local governments; Number of Response: 50; Frequency of Response: 10; Estimated Annual Burden: 1,500 hours.

2. Information Collection Requirements at 42 CFR 405.472, 431.460, 456.654, 466.70, 466.72, 466.74, 466.78, 466.80 and 466.94—0938-0445—These sections describe review functions to be performed by the PRO's and outlines the relationship among PRO's fiscal intermediaries, carriers, providers, practitioners and beneficiaries. Respondents: Business or other for-profit, Small business or organizations; Number of Response: 54; Frequency of Response: On occasion; Estimated Annual Burden: 70,139 hours.

OMB Desk Officer: Allison Herron.

As mentioned above, copies of the information collection clearance packages can be obtained by calling the Reports Clearance Officer, on one of the following numbers:

PHS: 202-245-2100
HCFA: 301-966-2088
FSA: 202-245-0652
SSA: 301-965-4149
OS: 202-245-6511
OHDS: 202-472-4415

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, DC 20503.

ATTN: Shannah Koss-McCallum.

Date: August 8, 1988.

James V. Oberthaler,

Deputy Assistant Secretary, Information Resources Management.

[FR Doc. 88-18252 Filed 8-11-88; 8:45 am]

BILLING CODE 4150-04-M

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Department of Health and Human Services (HHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on August 5, 1988.

Health Care Financing Administration

(Call Reports Clearance Officer on 301-594-1238 for copies of package)

1. Survey Report Forms and Instructions for ICF/MR—New—In order to participate in the Medicaid program as an ICF/MR, providers must meet Federal standards. The survey form is used to record provider's compliance with the individual standards and report it to the Federal government. Respondents: State or local governments; Number of Respondents: 4,315; Frequency of Response: 1; Estimated Annual Burden: 12,945 hours.

OMB Desk Officer: Allison Herron.

As mentioned above, copies of the information collection clearance packages can be obtained by calling the Reports Clearance Officer, on one of the following numbers:

PHS: 202-245-2100
HCFA: 301-594-1238
FSA: 202-245-0652
SSA: 301-965-4149
OS: 202-245-6511
OHDS: 202-472-4415

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, DC 20503.

ATTN: Shannah Koss-McCallum.

Date: August 8, 1988.

James E. Larson,

Acting Deputy Assistant Secretary, Information Resources Management.

[FR Doc. 88-18253 Filed 8-11-88; 8:45 am]

BILLING CODE 4150-04-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 88E-0210]

Determination of Regulatory Review Period for Purposes of Patent Extension; the Synchromed ™ Infusion Pump

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for The SynchroMed ™ Infusion Pump and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

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

FOR FURTHER INFORMATION CONTACT: I. David Wolfson, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 158(g)(3)(B).

FDA recently approved for marketing the medical device known as The SynchroMed ™ Infusion Pump which is indicated for the chronic intravascular infusion of floxuridine (FUDR) or doxorubicin hydrochloride (Adriamycin) and, when required, bacteriostatic water, physiological saline, and/or heparin. Subsequent to approval, the Patent and Trademark Office received a patent term restoration application for U.S. Patent No. 4,146,029 from Medtronic, Inc. The Patent and Trademark Office requested FDA's assistance in determining the product's eligibility for patent term restoration, and in a letter dated June 14, 1988, FDA advised the Patent and Trademark Office that the medical device had undergone a regulatory review period and that the medical device represented the first permitted commercial marketing or use. This **Federal Register** notice now represents FDA's determination of the product's regulatory review period.

FDA has determined that the applicable regulatory review period for The SynchroMed ™ Infusion Pump is 2,186 days. Of this time, 1,594 days occurred during the testing phase of the regulatory review period, while 592 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun:* March 22, 1982. FDA has verified the applicant's claim that the investigational device exemption was effective on March 22, 1982.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act:* August 1, 1986. The applicant claims that the premarket approval application (PMA) for the device (P860004) was submitted on January 30, 1986. However, FDA records indicate that the PMA was not sufficiently complete to allow the FDA review to begin until August 1, 1986.

3. *The date the application was approved:* March 14, 1988. FDA has verified the applicant's claim that the PMA (P860004) was approved on March 14, 1988.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 11, 1988, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 9, 1989, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 8, 1988.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 88-18292 Filed 8-11-88; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

Division of Research Resources; Meeting of the Minority Biomedical Research Support Subcommittee of the General Research Support Review Committee

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Minority Biomedical Research Support Subcommittee (MBRSS) of the General Research Support Review Committee (GRSRC), Division of Research (DRR), November 17-18, 1988, Building 31, Conference Room 9, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892.

This meeting will be open to the public on November 18, from 1:00 p.m. to adjournment to discuss policy matters relating to the Minority Biomedical

Research Support Program (MBRSP). Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on November 17, from 8:30 a.m. to 5 p.m. and November 18, from 8:30 a.m. to 12:00 p.m. for the review, discussion, and evaluation of individual grant applications.

The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mr. James Augustine, Information Officer, Division of Research Resources, National Institutes of Health, Building 31, Room 5B10, Bethesda, Maryland 20892, (301) 496-5545, will provide a summary of the meeting, and a roster of the committee members upon request. Dr. Lawrence J. Alfred, Executive Secretary, (301) 496-4390, will provide substantive program information upon request.

(Catalog of Federal Domestic Assistance Program No. 13.375, Minority Biomedical Research Support, National Institutes of Health)

Dated: August 2, 1988.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 88-18254 Filed 8-11-88; 8:45 am]

BILLING CODE 4140-01-M

National Arthritis and Musculoskeletal and Skin Diseases Advisory Council; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council to provide advice to the National Institute of Arthritis and Musculoskeletal and Skin Diseases on September 14 and 15, 1988, Wilson Hall, Building 1, National Institutes of Health, Bethesda, Maryland. The meeting will be open to the public September 14 from 8:30 a.m. to 12 noon to discuss administrative details relating to Council business and special reports. Attendance by the public will be limited to space available.

The meeting of the Advisory Council will be closed to the public on September 14 from 1 p.m. to adjournment on September 15 at approximately 12 noon in accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual grant applications. These deliberations could reveal confidential trade secrets or commerical property, such as patentable materials, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Further information concenring the Council meeting may be obtained from Dr. Steven J. Hausman, Executive Secretary, National Arthritis and Musculoskeletal and Skin Diseases Advisory Council, NIAMS, Westwood Building, Room 403, Bethesda, Maryland 20892, (301) 496-7495.

A summary of the meeting and roster of the members may be obtained from the Committee Management Office, NIAMS, Building 31, Room 4C32, National Institutes of Health, Bethesda, Maryland 20892, (301) 496-0803.

(Catalog of Federal Domestic Assistance Program No. 13.846, Arthritis, Bone and Skin Diseases, National Institutes of Health)

Dated: August 2, 1988.

Betty J. Beveridge,

NIH, Committee Management Officer.

[FR Doc. 88-18256 Filed 8-11-88; 8:45 am]

BILLING CODE 4140-01-M

National Cancer Institute, Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the Development Therapeutics Contracts Review Committee, National Cancer Institute, National Institutes of Health, November 17-18, 1988, Bethesda Holiday Inn, Pennsylvania Conference Room, 8120 Wisconsin Avenue, Bethesda, MD 20814.

This meeting will be open to the public on November 17 from 8 a.m. to 8:30 a.m. to discuss administrative details. Attendence by the public will be limted to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552(c)(6), Title 5, U.S.C. and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on November 17 from 8:30 a.m. to recess, and on November 18 from 8 a.m. to adjournment for the review, discussion, and evaluation of individual contract proposals. The proposals and the discussion could reveal confidential trade secrets or commercial property such as patentable material and personnal information concerning individuals associated with the proposals, disclosure of which would constitute a clearly unwarranted invasion of personnel privacy.

Mrs. Winifred Lumsden, the Committee Management Officer, National Cancer Institute Building 31, Room 10A-06, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892 (301-496-5708), will provide a summary of the meeting and a roster of the committee members upon request.

Dr. Kendall G. Powers, Executive Secretary, Development Therapeutics Contracts Review Committee, National Cancer Institute, Westwood Building, Room 805, National Institutes of Health, Bethesda, Maryland 20892 (301-496-7575) will provide substantive program information, upon request.

Dated: August 2, 1988.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 88-18255 Filed 8-11-88; 8:45 am]

BILLING CODE 4140-01-M

National Institute of Neurological and Communicative Disorders and Stroke; Meetings

Pursuant to Pub. L. 92-463, notice is hereby given of the meetings of the committees of the National Institute of Neurological and Communicative Disorders and Stroke.

These meetings will be open to the public to discuss administrative details or other issues relating to committee business as indicated in the notice. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of meetings, rosters, of committee members, and other information pertaining to the meetings can be obtained from the Executive Secretary indicated.

Name of Committee: National Advisory Neurological and Communicative Disorders and Stroke Council and Its Planning Subcommittee

Date: October 5, 1988 (Planning Subcommittee).

Place: National Institutes of Health, Building 31, Conference Room 8A28,

9000 Rockville Pike, Bethesda, Maryland 20892.

Open: 1 p.m.–3 p.m.

Agenda: To discuss program planning, program accomplishments and special reports.

Closed: 3 p.m.–5 p.m.

Closure Reason: For review of grant applications.

Dates: October 6–7, 1988 (Council).

Place: National Institutes of Health, Building 31C, Conference Room 6, Bethesda, Maryland 20892.

Open: October 6, 9 a.m.–1 p.m.

Agenda: To discuss program planning, program accomplishments and special reports.

Closed: October 6, 1 p.m.–recess, October 7, 8:30 a.m.–adjournment.

Closure Reason: For review of grant applications.

Executive Secretary: John C. Dalton, Ph.D., Associate Director for Extramual Activities, NINCDS, National Institutes of Health, Bethesda, Maryland 20892, Telephone: 301/496–9248.

Name of Committee: Neurological Disorders Program Project Review A Committee

Dates: October 13–15, 1988.

Place: Ramada Inn, Bethesda, 8400 Wisconsin Avenue, Bethesda, Maryland 20814.

Open: October 13—1 p.m.–1:30 p.m.

Agenda: To discuss program planning, program accomplishments and special reports.

Closed: October 13—1:30 p.m.–recess, October 14—7:30 a.m.–recess, October 15—7:30 a.m.–adjournment.

Closure Reason: To review grant applications.

Executive Secretary: Dr. Herbert Yellin, Federal Building, Room 9C–14, National Institutes of Health, Bethesda, Maryland 20892, Telephone: 301/496–9223.

Name of Committee: Neurological Disorders Program Project Review B Committee

Dates: October 14–16, 1988.

Place: Holiday Inn, Civic Center, 50 Eight Street, San Francisco, California 94103.

Open: October 14—7:30 p.m.–8 p.m.

Agenda: To discuss program planning, program accomplishments and special reports.

Closed: October 14—8 p.m.–recess, October 15—8 a.m.–recess, October 16—8 a.m.—adjournment.

Closure Reason: To review grant applications.

Executive Secretary: Dr. A. Beau White, Federal Building, Room 9C–14, National Institutes of Health, Bethesda, Maryland 20892, Telephone: 301/496–9223.

Name of Committee: Communicative Disorders Review Committee

Date: October 20–21, 1988.

Place: Holiday Inn, Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, Maryland 20815.

Open: October 20—8:30 a.m.–9 a.m.

Agenda: To discuss program planning, program accomplishments and special reports.

Closed: October 20—9 a.m.–recess, October 21—8:30 a.m.–adjournment.

Closure Reason: To review grant applications.

Executive Secretary: Dr. Marilyn Semmes, Federal Building, Room 9C–14, National Institutes of Health, Bethesda, Maryland 20892, Telephone: 301/496–9223.

(Catalog of Federal Domestic Assistance Program No. 13.853, Clinical Basis Research; No. 13.854, Biological Basis Research)

Dated: August 2, 1988.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 88–18257 Filed 8–11–88; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Co-030-08-4212-21]

Montrose District Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given in accordance with 43 CFR Subpart 1784, that a meeting of the Montrose District Advisory Council will be held September 13 and 14, 1988 in Delta and Montrose, Colorado.

DATE: Meetings are scheduled September 13 and 14, 1988.

ADDRESS: For further information contact Debbie Pietrzak, Bureau of Land Management (BLM), Montrose District Office, 2465 South Townsend Avenue, Montrose, CO 81401; Telephone (303) 249–7791.

SUPPLEMENTARY INFORMATION: The Council will have a field tour to the proposed National Guard firing range near Delta, Colorado on September 13, 1988, from 1:00 p.m. to 5:00 p.m. Following the field tour, the Council will accept public comments on the proposal at 7:30 p.m. at the Forest Service Supervisor's Office, 2250 Highway 50, Delta, Colorado. The length of the comment period will be determined by the number of individuals who wish to comment. Commentors may be required to limit the length of their oral statements.

The Council will reconvene at 9:00 a.m. September 14, 1988 at the BLM District Office in Montrose.

Agenda—September 14:

9:00 a.m. Public comment period.

9:30 a.m. Formulation of Council resolution on National Guard proposal; election of officers.

10:00 a.m. Resource Area updates on: resource management planning, uranium mill tailings disposal, low level radioactive waste disposal, Hovenweep expansion proposal, wild horse management.

11:30 a.m. Slide presentation on archaeology.

12 noon Adjourn.

The field tour and meetings of the Council are open to the public. Individuals wishing to participate in the tour must provide their own transportation. Members of the public may meet the Council at the BLM District Office in Montrose at 1:00 p.m. or at the Forest Service Supervisor's Office in Delta at 1:30 p.m. on the day of the field tour.

Dated: August 5, 1988.

Robert S. Schmidt,

Acting District Manager.

[FR Doc. 88–18280 Filed 8–11–88; 8:45 am]

BILLING CODE 4310-JB-M

[NV-930-08-4212-11; N-971]

Opening Order, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This notice provides for opening of certain lands for direct sale to Douglas County, Nevada.

EFFECTIVE DATE: August 12, 1988.

FOR FURTHER INFORMATION CONTACT: James W. Elliott, District Manager, Carson City District Office, Bureau of Land Management, 1535 Hot Springs Road, Carson City, Nevada 89701, (702) 882–1631.

SUPPLEMENTARY INFORMATION: In 1967, title to 97.05 acres of public land was transferred to Douglas County pursuant to the Recreation and Public Purposes Act (43 CFR Parts 869, 869–1 to 869–4). By quitclaim deed executed April 7, 1988, the following described 40 acres were reconveyed to the United States as Douglas County would now like to acquire unrestricted title to the lands

pursuant to section 203 of the Federal Land Policy and Management Act (43 U.S.C. 1713):

Mount Diablo Meridian, Nevada

T. 12 N., R. 21 E.,
Sec. 18, W½SW¼NE¼, E½SE¼NW¼.

At 10:00 a.m., on August 12, 1988, the lands described above will be open to disposal pursuant to section 203 of the Federal Land Policy and Management Act, for the purpose of consummating a non-competitive sale to Douglas County, subject to any valid existing rights, the provisions of existing withdrawls, and the requirements of applicable laws, rules, and regulations.

The land will remain closed to all other forms of appropriation including the mining laws.

Edward F. Spang,

State Director.

[FR Doc. 18321 Filed: 8-11-88; 8:45 am]

BILLING CODE 4310-HC-M

National Park Service

Upper Delaware Scenic and Recreational River; Meeting of Upper Delaware Citizens Advisory Council

AGENCY: National Park Service; Upper Delaware Citizens Advisory Council.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the date of the forthcoming meeting of the Upper Delaware Citizens Advisory Council. Notice of this meeting is required under the Federal Advisory Committee Act.

DATE: August 26, 1988, 7:00 p.m.[1]

Inclement Weather Reschedule Date: September 9, 1988.

ADDRESS: Town of Tusten Hall, Narrowsburg, New York.

FOR FURTHER INFORMATION CONTACT: John T. Hutzky, Superintendent; Upper Delaware Scenic and Recreational River, P.O. Box C, Narrowsburg, NY 12764-0159; 717-729-8251.

SUPPLEMENTARY INFORMATION: The Advisory Council was established under section 704(f) of the National Parks and Recreation Act of 1978, Pub. L. 95-625, 16 U.S.C. 1724 note, to encourage maximum public involvement in the development and implementation of the plans and programs authorized by the Act. The Council is to meet and report to the Delaware River Basin Commission, the Secretary of the Interior, and the Governors of New York and Pennsylvania in the preparation and implementation of the management plan, and on programs which relate to land and water use in the Upper Delaware region. The agenda for the meeting will surround planning for October 9, 1988, forestry management seminar, Council membership, continued discussion of issues relating to the strand, and Barnes Landfill developments.

The meeting will be open to the public. Any member of the public may file with the Council a written statement concerning agenda items. The statement should be addressed to the Upper Delaware Citizens Advisory Council, P.O. Box 84, Narrowsburg, NY 12764. Minutes of the meeting will be available for inspection four weeks after the meeting, at the permanent headquarters of the Upper Delaware Scenic and Recreational River; River Road, 1¾ miles north of Narrowsburg, New York; Damascus Township, Pennsylvania.

James W. Coleman, Jr.,

Regional Director, Mid-Atlantic Region.

[FR Doc. 88-18293 Filed 8-11-88; 8:45 am]

BILLING CODE 4310-70-M

[1] Announcements of cancellation due to inclement weather will be made by radio stations WDNH, WDLC, WSUL, and WVOS.

INTERSTATE COMMERCE COMMISSION

Agricultural Cooperative; Intent To Perform Interstate Transportation for Certain Nonmembers

Date: August 9, 1988.

The following Notices were filed in accordance with section 10526(a)(5) of the Interstate Commerce Act. These rules provide that agricultural cooperatives intending to perform nonmember, nonexempt, interstate transportation must file the Notice, Form BOP 102, with the Commission within 30 days of its annual meetings each year. Any subsequent change concerning officers, directors, and location of transportation records shall require the filing of a supplemental Notice within 30 days of such change.

The name and address of the agricultural cooperative (1) and (2), the location of the records (3), and the name and address of the person to whom inquiries and correspondence should be addressed (4), are published here for interested persons. Submission of information which could have bearing upon the propriety of a filing should be directed to the Commission's Office of Compliance and Consumer Assistance, Washington, DC 20423. The Notices are in a central file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, DC.

(1) Farmers Union Cooperative Transport, Inc.
(2) P.O. Box 118, Stetsonville, WI 54480
(3) N983 Hwy 13, Stetsonville, WI 54480
(4) Mr. Larry Ray, P.O. Box 118, Stetsonville, WI 54480

Noreta R. McGee,

Secretary.

[FR Doc. 88-18260 Filed 8-11-88; 8:45 am]

BILLING CODE 7035-01-M

Intent To Engage in Compensated Intercorporate Hauling Operations

This is to provide notice as required by 49 U.S.C. 10524(b)(1) that the named corporations intend to provide or use compensated intercorporate hauling operations as authorized in 49 U.S.C. 10524(b).

A. 1. Parent corporation and address of principal office: Medical Energy Generation Associates, Inc., 184 High Street, Boston, MA 02110.

2. Wholly-owned subsidiaries which will participate in the operations, and States of incorporation:

Medical Energy Generation Associates of Kentucky, Inc. (a Delaware corporation)
Medical Energy Generation Associates of Pennsylvania, Inc. (a Delaware corporation)
Medical Energy Generation Associates of Massachusetts, Inc. (a Delaware corporation)
Medi-Waste, Ltd. (a New York corporation)

B. 1. Parent corporation and address of principal office: Texas Industries, Inc., 8100 Carpenter Freeway, Dallas, Texas 75247.

2. Wholly-owned subsidiaries which will participate in the operations, and state(s) of incorporation:

Texas Industries, Inc.—Delaware
Aggregates Railway Corporation—Louisiana
Athens Brick Company—Delaware
Brookhollow Corporation—Delaware
Creole Corporation—Delaware
Dolphin Construction Company—Louisiana
East Louisiana Railway Company—Louisiana
Fort Worth Sand & Gravel Company, Inc. (Inactive)—Texas
L I Precast Company—Louisiana
Louisiana Industries, Inc.—Louisiana
Louisiana Industries Prestressed Corp.—Delaware
Mississippi Industries, Inc. (Inactive)—Mississippi
National Concrete Industries, Inc. (Inactive)—Delaware
Poway Development Corporation—Delaware

The George Rackle & Sons Company (Inactive)—Ohio
TXI Transportation Company—Texas
Southern States Mining Company—Tennessee
Southwestern Financial Corporation—Delaware
Texas Industries Foundation—Texas (Non-Profit)
Texas Lightweight Aggregate Company (Inactive)—Texas
Thurber Coal Company—Texas
Tri-State Industries, Inc.—Tennessee
TXI Aviation, Inc.—Texas
TXI Cement Company—Delaware
TXI Structural Products, Inc.—Delaware
United Cement Company—Mississippi
Brookhollow of Alexandria, Inc.—Louisiana
Brookhollow/Arlington, Inc.—Texas
Brookhollow Hotel Corporation (formerly The 8100 Corporation)—Texas
Brookhollow of Houston, Inc.—Texas
Brook Hollow Properties, Inc.—Texas
Empire Central Investment Corporation—Texas
Brookhollow of North Carolina, Inc.—North Carolina
Brookhollow of Virginia, Inc.—Virginia
Brookhollow/Arlington Properties, Inc.—Texas
Brookhollow/Arlington P.O.D. I, Inc.—Texas
Brookhollow/Riverside, Inc.—Texas
Brookhollow Two Restaurant Corporation—Texas
Brookhollow of Florida, Inc.—Florida
Brookhollow/Greensboro Properties, Inc.—North Carolina
Brookhollow/Lewisville, Inc.—Texas
Ferrco Dallas, Inc.—Texas
TA Joist, Inc.—Delaware
Brookhollow Plaza, Inc.—Texas

Noreta R. McGee,

Secretary.

[FR Doc. 88-18261 Filed 8-11-88; 8:45 am]

BILLING CODE 7035-01-M

[No. OP4-MCF-324]

Motor Carrier Finance Applications; Decision-Notice

The following applications 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 49 CFR 1182.1.

Persons wishing to oppose an application must follow the rules under 49 CFR 1182.2. If the protest includes a request for oral hearing, the request shall meet the requirements of 49 CFR 1182.3 and shall include the required certifications. Failure reasonable to oppose will be construed as a waiver of opposition and participation in the proceeding.

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.

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.

Findings: The findings for these applications are set forth at 49 CFR 1182.6.

Decided: August 5, 1988.

By the Commission, Motor Carrier Board, Members Thomas, Taylor and Brown. (Member Brown not participating)

Noreta R. McGee,

Secretary.

MC-F-19207, filed July 8, 1988. William H. Shafer and Stephen M. Summerton, 331 Danbury Road, Wilton, CT 06897—Control—Regency Limousine, Inc., and Marquis Leasing, Inc., 331 Danbury Road, Wilton, CT 06897. *Representative:* William F. King, Suite 1018, 4660 Kenmore Ave., Alexandria, VA 22304. William H. Shafer and Stephen M. Summerton, both noncarrier individuals, each own 50 percent of the shares of Regency Limousine, Inc., (RLI) (MC-148906) and are officers and directors of that company. RLI holds passenger carrier authority to conduct special and charter operations between points in the U.S., including AK, but excluding HI. Shafer and Summerton each own 50 percent of the shares of Marquis Leasing, Inc. (MLI), and are officers and directors of that corporation. MLI is now an noncarrier, but by a concurrently filed application seeks passenger carrier authority to conduct special and charter operations identical in territorial scope to RLI's authority. Shafer and Summerton seek authority to control RLI and MLI when the latter also becomes a regulated carrier pursuant to the initial grant of authority it seeks in No. MC-211649.

[FR Doc. 88-18226 Filed 8-11-88; 8:45 am]

BILLING CODE 7035-01-M

[No. 40165]

Adoption of the Railroad Accounting Principles Board's Recommendation on Its Data Integrity Principle in Reports Prepared Using Agreed-Upon Procedures

AGENCY: Interstate Commerce Commission.

ACTION: Notice of decision.

SUMMARY: The Commission adopts the recommendation by the Railroad Accounting Principles Board (RAPB) regarding its Data Integrity Principle. A notice of proposed rulemaking in this proceeding was served March 30, 1988, and published in the **Federal Register** on March 31, 1988 (53 FR 10410). Specifically, the Commission would require that independent public accountants (IPA's) comply with Statement on Auditing Standards No. 35 (SAS No. 35) and the American Institute of Certified Public Accountants' (AICPA) *Statement on Standards for Attestation Engagements* (Attestation Standards) [1] when preparing railroad audit reports using agreed-upon procedures.[2]

DATE: The adoption of these standards will become effective on September 11, 1988.

FOR FURTHER INFORMATION CONTACT: William F. Moss, III, (202) 275-7510. [TDD for hearing impaired: (202) 275-1721]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to Dynamic Concepts, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423 or call (202) 289-4357. Assistance for the hearing impaired is available through TDD services on (202) 275-1721.

This action will not significantly affect either the quality of the human environment or energy conservation. This decision will not have a significant economic impact on a substantial number of small entities.

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[1] SAS No. 35, *Special Reports—Applying Agreed-Upon Procedures to Specified Elements, Accounts, or Items of a Financial Statement*, was issued by the Auditing Standard Board of the AICPA in April, 1981.

Statement on Standards for Attestation Engagements was issued by the Auditing Standards Board and the Accounting and Review Services Committee under the authority of the AICPA in March, 1986.

[2] Ex Parte No. 460, *Certification of Railroad Annual Report R-1 by Independent Accountant*, served on October 11, 1985, established that IPA's shall perform rail audits using agreed-upon procedures.

This revision will be submitted to the Office of Management and Budget (OMB) for review under section 3504(h) of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). Respondents may direct comments to OMB by addressing them to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Desk Officer for Interstate Commerce Commission, Washington, DC 20503.

Authority: 49 U.S.C. 11142 and 11145; and 5 U.S.C. 553.

Decided: August 5, 1988.

By the Commission, Chairman Gradison, Vice Chairman Andre, Commissioners Sterrett, Simmons, and Lamboley.

Noreta R. McGee,

Secretary.

[FR Doc. 88-18259 Filed 8-11-88; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167; Sub-No. 1088X]

Consolidated Rail Corp.; Abandonment Exemption

Applicant has refiled a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon its 23.95-mile line of railroad between milepost 66.05 at Cadiz Junction, Harrison County, OH, and milepost 90.0 in Dennison, Tuscarawas County, OH.[1]

Applicant has certified that (1) no local traffic has moved over the line for at least 2 years, (2) any overhead traffic on the line can be rerouted over other lines, and (3) no formal complaint filed by a user of rail service on the line (or by a State or local governmental entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or any U.S. District Court, or has been decided in favor of the complainant within the 2-year period. The appropriate State agency has been notified in writing at least 10 days prior to the filing of this notice.

As a condition to use of this exemption, any employee affected by the abandonment shall be protected pursuant to *Oregon Short Line R. Co.-Abandonment-Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance has been received, this exemption will be effective September 11, 1988, unless stayed pending reconsideration. Petitions to stay regarding matters that do not involve environmental issues[2] and formal expressions of intent to file an offer of financial assistance under 49 CFR 1152.27(c)(2)[3] must be filed by August 22, 1988, and petitions for reconsideration,[4] including environmental, energy, and public use concerns, must be filed by September 1, 1988, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission must be sent to applicant's representative: Charles E. Mechem, Consolidated Rail Corporation, Room 1138 Six Penn Center Plaza, Philadelphia, PA 19103-2959.

If the notice of exemption contains false or misleading information, use of the exemption is void *ab initio.*

Applicant has filed an environmental report which addresses environmental or energy impacts, if any, from this abandonment.

The Section of Energy and Environment (SEE) will prepare an environment assessment (EA). SEE will serve the EA on all parties by August 17, 1988. Other interested persons may obtain a copy of the EA from SEE by writing to it (Room 3115, Interstate Commerce Commission, Washington, DC 20423) or by calling Carl Bausch, Chief, SEE at (202) 275-7316.

A notice to the parties will be issued if use of the exemption is conditioned upon environmental or public use conditions.

Decided: August 4, 1988.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 88-18262 Filed 8-11-88; 8:45 am]

BILLING CODE 7035-01-M

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[1] Applicant's notice of exemption filed on May 24, 1988, was rejected because it did not meet certain environmental reporting requirements. Applicant's notice of exemption filed June 17, 1988, and published July 7, 1988, in the **Federal Register** was withdrawn because it contained an erroneous statement. All pleadings and correspondence submitted in response to prior notices remains part of the record and need not be refiled.

[2] A stay will be routinely issued by the Commission in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Section of Energy and Environment in its independent investigation) cannot be made prior to the effective date of the notice of exemption. *See* Ex Parte No. 274 (Sub-No. 8), *Exemption of Out-of-Service Rail Lines* (not printed), served March 8, 1988.

[3] *See Exemption of Rail Line Abandonments or Discontinuance—Offers of Financial Assistance,* 4 I.C.C. 2d 164 (1987), and final rules published in the **Federal Register** December 22, 1987 (52 FR 48440-48446).

[4] The comments opposing the proposed abandonment that already have been filed as well as any other comments and petitions for reconsideration or stay that may be filed by the August 22, 1988 and September 1, 1988 due dates will be addressed by the Commission in a subsequent decision(s).

DEPARTMENT OF LABOR

Office of the Secretary

Labor Advisory Committee for Trade Negotiations and Trade Policy

The Secretary of Labor and the United States Trade Representative have taken steps to renew the Labor Advisory Committee for Trade Negotiations and Trade Policy. The Committee and subcommittees will be chartered pursuant to section 135(c) (1-2) of the Trade Act of 1974 (19 U.S.C. 2155(c) (1-2), as amended, and Executive Order No. 11846, March 27, 1975 (19 U.S.C. 2111 nt). The charter of the Committee will be filed 15 days from the date of this notice.

The Labor Advisory Committee for Trade Negotiations and Trade Policy consults with, and makes recommendations to the Secretary of Labor and to the United States Trade Representatives on issues of general policy matters concerning labor and trade negotiations, operations of any trade agreement once entered into, and other matters arising in connection with the administration of the trade policy of the United States.

The Committee will meet at irregular intervals at the call of the Secretary of Labor and the United States Trade Representative. The frequency of committee meetings will be approximately two or three times per year, depending upon the needs of the Secretary of Labor and the United States Trade Representative. The Steering Subcommittee will meet monthly. Other subcommittees may meet on an ad hoc basis.

Representatives from the private sector wishing further information or to be considered for appointment to serve on the committee should contact: Mr. Fernand Lavallee, Executive Secretary, Labor Advisory Committee, Frances Perkins Department of Labor Building, Room S5325, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone: (202) 523-6565.

Signed at Washington, DC, this 8th day of August 1988.

Ann McLaughlin,

Secretary of Labor.

[FR Doc. 88-18227 Filed 8-11-88; 8:45 am]

BILLING CODE 4510-23-M

Employment and Training Administration

[TA-W-20,596]

Haven-Busch Co., Grandville, MI; Negative Determination Regarding Application for Reconsideration

By an application dated July 5, 1988 the International Association of Bridge, Structural & Ornamental Iron Workers, AFL-CIO, Local #688 requested administrative reconsideration on the subject petition for trade adjustment assistance. The denial notice was signed on June 6, 1988 and published in the **Federal Register** on June 21, 1988 (53 FR 23317).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

Workers at Grandville produced fabricated structural steel mainly for the construction of auto plants.

The union claims that imported steel adversely affected worker separations at Grandville because many of the foreign steel producers have found ways to get around the voluntary and mandatory restrictions on imports. It is also claimed that increased imports of autos contributed to the depressed auto plant construction market.

Findings in the investigation show that the increased import criterion of the Group Eligibility Requirements of the Trade Act of 1974 were not met in 1987 or in the first quarter of 1988. The Findings show that U.S. imports of fabricated structural steel declined absolutely and relative to domestic shipments in 1987 compared to 1986. U.S. imports of fabricated structural steel continued to decline absolutely in the first quarter of 1988 compared to the same quarter in 1987. In addition, there were increased sales of fabricated structural steel produced at the Grandville facility in the first quarter of 1988 compared to the same quarter in 1987. A list of major projects not awarded to Haven-Busch or cancelled in 1986 and 1987 was submitted by the company. The findings show that the projects which were not cancelled were awarded to other domestic fabricators. Cancelled projects had a substantial adverse impact on Haven-Busch's sales.

The findings also show that the Grandville plant ceased fabricating operations in February 1988 and went into a new business of marketing European building products. The products are electronic revolving doors and tubular space frames used on roofing for atrium settings in hotels. These products are not like or directly competitive with the fabricated structural steel formerly produced at Gransville. According to company officials, the major reasons for the restructuring was the capacity of the fabricated structural steel industry far exceeded domestic demand and the negative impact of the 1986 Tax Law on depreciation and capital expenditures. As a result of the restructuring decision, the company did not submit any bids for steel fabrication projects in 1988.

With respect to the union's claim concerning imports of autos adversely affecting fabricated structural steel production for auto plant construction, the Trade Act, in determining import injury, allows only increased imports of articles like or directly competitive with those produced by the workers' firm. Imported autos are not like or directly competitive with fabricated structural steel for auto plants. Imports of fabricated structural steel must be considered in determining an import impact on workers producing fabricated structural steel.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 28th day of July 1988.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 88-18232 Filed 8-11-88; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-20,631 and TA-W-20, 632]

White Consolidated Industries; Belding Products Co., Belding, MI; Greenville Products Co., Greenville, MI; Negative Determination Regarding Application for Reconsideration

By an application dated July 11, 1988 the United Auto Workers Locals #137 and #1554 requested administrative reconsideration of the Department's negative determination on the subject petition for trade adjustment assistance. The initial petition was filed by Locals #137 and #1554 of the United Auto Workers on behalf of workers at Belding Products Company, Belding, Michigan and Greenville Products Company, Greenville, Michigan. The denial notice was signed on June 13, 1988 and published in the **Federal Register** on June 28, 1988 (53 FR 24379).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

In addition to newspaper clippings and a memorandum concerning the export of room air conditioner kits to China, the union submitted production data on room air conditioners at Belding for model years 1972 to 1988. The union stated that corporate sales of room air conditioners decreased in 1988 and customers increased their import purchases of room air conditioners.

Findings in the investigation show that production declines and worker separations in 1988 at Belding were the result of a domestic transfer of production from Belding, Michigan to another corporate plant in Edison, New Jersey. Prior to the shutdown, which occurred as part of a plan developed in January 1987, air conditioner production and worker employment at Belding increased in 1987 compared to 1986. As production at Belding declined in the first quarter of 1988 compared to the same quarter in 1987, production at Edison increased, reflecting the transfer. Corporate production and sales of room air conditioners increased in the first six months of 1988 compared to the same period in 1987. Accordingly, the Department sees no adverse impact on room air conditioners.

Investigation findings also show that the purchase of air conditioning kits by China are for training and any assembled kits are intended only for use in China. Export sales would not form a basis for certification.

Workers at Greenville Products Company, Greenville, Michigan produced refrigerators. Sales of refrigerators increased in 1987 compared to 1986 and in the first quarter of 1988

compared to the same quarter of 1987. Production worker employment at Greenville increased over the same periods. Layoffs at Greenville were attributed to bumping privileges exercised by employees separated from WCI's Belding Products Company because of the domestic transfer of production.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the fact which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 4th day of August 1988.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 88-18322 Filed 8-11-88; 8:45 am]

BILLING CODE 4310-30-M

Job Training Partnership Act; Indian and Native American Employment and Training Programs

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of final designation procedures for grantees.

SUMMARY: This document contains final procedures by which the Department of Labor (DOL) will designate grantees for Indian and Native American Employment and Training Programs under the Job Training Partnership Act (JTPA). The next cycle of such designation actions will cover JTPA Program Years 1989 and 1990 (July 1, 1989 through June 30, 1991). Applicants selected for funding in PY 1989 also will be funded in PY 1990 if applicable regulatory requirements are met, and funds are available. This notice provides necessary information to prospective grant applicants to enable them to submit appropriate requests for designation.

EFFECTIVE DATE: August 15, 1988.

ADDRESS: Send one original and two copies of the Advance and final Notices of Intent to Mr. Herbert Fellman, Chief, Division of Indian and Native American Programs, U.S. Department of Labor, Room N-4641, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: ANOI/NOI Desk.

SUPPLEMENTARY INFORMATION: Proposed designation procedures for Indian and Native American Employment and Training Programs under section 401 of JTPA were published in the **Federal Register** on June 17, 1988 (53 FR 22746) for the purpose of soliciting public comment. Written comments were to be sent to the attention of Paul A. Mayrand, Director, Office of Special Targeted Programs (OSTP) on or before July 18, 1988. No written comments had been received as of that date. Accordingly, the procedures for JTPA, section 401 Indian and Native American grantees proposed at 53 FR 22746 (June 17, 1988) are adopted in final for the Program Year 1989–1990 designation cycle.

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Introduction: Scope and Purpose of Notice

Section 401 of JTPA authorizes programs to serve the employment and training needs of Indians and Native Americans.

Requirements for these programs are set forth in JTPA and in the regulations at 20 CFR Part 632. Pursuant to these requirements, the Department of Labor (DOL) selects entities for funding under JTPA section 401, and designates such entities as Native American grantees, contingent on all other grant award requirements being met. This notice describes how DOL will make such designation decisions for the period of Program Years (PYs) 1989 and 1990 (July 1, 1989 through June 30, 1991). It provides necessary information to prospective grant applicants to enable them to submit appropriate requests for designation.

The amount of JTPA section 401 funds to be awarded to designated Native American grantees is determined under procedures described at 20 CFR 632.171 and not through this designation process. The specific organization eligibility and application requirements for designation are contained at 20 CFR 632.10 and 632.11. Any organization interested in being designated as a Native American grantee should be aware of and comply with these requirements.

I. General Designation Principles

Based on JTPA and applicable regulations, the following general principles are intrinsic to the designation process:

(1) Applicants for designation shall comply with the requirements found at 20 CFR Part 632 regardless of their apparent standing in the preferential hierarchy. The basic eligibility, application and designation requirements are found in Subpart B of Part 632.

(2) The nature of this program is such that Indians and Native Americans in an area are entitled to program services, and are best served by a responsible organization directly representing them and designated pursuant to the applicable regulations. JTPA and the governing regulations give clear preference to Native American-controlled organizations. That preference is the basis for the steps which will be followed in designating grantees.

(3) A State-recognized or federally recognized tribe, band, or group on its reservation is given absolute preference over any other organization if it has the capability to administer the program and meets all regulatory requirements. This preference applies only to the area within the reservation boundaries. A reservation organization which may have its service area given to another qualified organization for reasons specified in the regulations will be given a future opportunity to reestablish itself as the designated grantee, should it so desire.

In the event that such a tribe, band, or group (including an Alaskan Native entity) is not designated to serve such groups, the DOL will consult with the governing body of such entities as provided at 20 CFR 632.10(e). Such consultation may be accomplished in writing, in person, or by telephone, as time and circumstances permit.

(4) In designating Native American grantees for off-reservation areas, DOL will provide preference to Indian and Native American-controlled organizations as described in 20 CFR 632.10(f) and as further clarified in this notice.

(5) Special employment and training services for Indian and Native American people have been provided through an established service delivery network for the past fourteen years under the authority of JTPA Section 401 and its predecessor, section 302 of the repealed Comprehensive Employment and Training Act (CETA). The DOL intends to exercise its designation authority to preserve the continuity of such services and to prevent the undue fragmentation of existing service areas. Consistent with present regulations and other provisions of this notice, this will include preference for those Native

American organizations with an existing capability to deliver employment and training services within an established service area. Such preference will be identified through input from the Chief of DOL's Division of Indian and Native American Programs (DINAP) and the Director of DOL's Office of Special Targeted Programs (OSTP), and through the use of the rating system described in this notice. Unless a non-incumbent applicant in the same preferential hierarchy as an incumbent applicant grantee can demonstrate that it is significantly superior overall to the incumbent, the incumbent will be designated, if it otherwise meets all of the requirements for redesignation.

II. Advance Notice of Intent

The purpose of the Advance Notice of Intent process is to provide Section 401 applicants, prior to the submission of a final Notice of Intent, with information relative to potential competition. While DOL encourages the resolution of competitive requests prior to final submission, the Advance Notice of Intent process also serve to alert those whose differences cannot be resolved of the need to submit a complete final Notice of Intent.

Although the Advance Notice of Intent process is not mandated by the regulations, participation in the advance process by prospective section 401 applicants is strongly recommended. The Advance Notice of Intent process allows the applicant to identify potential competitors, to resolve conflicts if possible, and to prepare a final Notice of Intent with advance knowledge of potential competing requests.

It should be emphasized, however, that the Advance Notice of Intent process does not ensure that all potential competitors have been identified. Some applicants may opt not to submit an Advance Notice of Intent; others may change service area requests in the final Notice of Intent. Therefore, as noted above, final submissions should be prepared with this possibility in mind.

By October 1 of the year preceding a designation year, all organizations interested in being designated as Section 401 grantees should submit an original and two copies of an Advance Notice of Intent. An organization may submit only one Advance Notice of Intent for any and all areas for which it wants to be considered. Advance Notices are to be sent to the following address: Mr. Herbert Fellman, Chief, Division of Indian and Native American Programs, U.S. Department of Labor, Room N-4641, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: ANOI/NOI Desk.

The Standard Form (SF) 424 is no longer used for the advance notification process. As in the PY 1987-1988 designation cycle, DOL will utilize the Advance Notice of Intent. This allows DOL to expedite the identification of potentially competitive applicants.

Complete instructions will be mailed to all current grantees on or about August 15. Incumbents will also receive a description of their present service area at this time. New applicants may request copies of the Advance Notice instructions by writing to: Mr. Herbert Fellman, Chief, Division of Indian and Native American Programs, U.S. Department of Labor, Room N-4641, 200 Constitution Avenue, NW., Washington, DC 20210.

The first step in the designation process is to determine which areas have more than one potential applicant for designation. For those areas for which more than one organization submits an Advance Notice of Intent, each such organization will be notified of the situation, and will be apprised of the identity of the other organization(s) applying for that area. Such notification will consist of providing affected applicants with copies of all Advance Notices of Intent submitted for their area. The notification will occur on or about November 15. The notification will state that organizations are encouraged to work out any jurisdictional disputes among themselves, and to submit a final Notice of Intent by the required postmark or hand delivered deadlines or withdraw their Advance Notice.

Under the Advance Notice of Intent process, it is DOL policy that to the extent possible within the regulations, service areas and the organizations operating in those areas be determined by the community to be served by the program. In the event the Native American community cannot resolve differences, the notification will inform parties that they should take special care with their final Notices of Intent to ensure that they are complete and fully responsive to all matters covered by the preferential hierarchy and rating systems discussed in this notice.

Information provided in the Advance Notice of Intent process shall not be considered as a final submission as referenced at 20 CFR 632.11. The Advance Notice is a procedural mechanism to facilitate the designation process. The regulations do not provide for formal application for designation through the Advance Notice.

III. Notice of Intent

All applicants will submit an original and two copies of a final Notice of Intent, postmarked no later than January 1, 1989, consistent with the regulations at 20 CFR 632.11. Final Notices of Intent may also be delivered in person not later than the close of business on the first business day of the designation year. *Exclusive of charts or graphs and letters of support, the Notice of Intent should not exceed 75 pages of double-spaced unreduced type.*

Final Notices of Intent are to be sent to the following address: Mr. Herbert Fellman, Chief, Division of Indian and Native American Programs, U.S. Department of Labor, Room N-4641, 200 Constitution Ave., NW., Washington, DC 20210. Attention: ANOI/NOI Desk.

The regulations permit current grantees requesting their existing service areas to submit a Standard Form 424 in lieu of a complete application. As noted earlier in this notice, current grantees, other than tribes, bands, or groups (including Alaskan Native entities) requesting their existing areas, are encouraged to consider submitting a full Notice of Intent even if their service area request has not changed.

Although organizations are encouraged to alter their area requests to minimize or avoid overlap with other organizations, they should not add territory to that identified in the Advance Notice of Intent. Unless currently designated for such areas, any organization applying on January 1 for noncontiguous areas shall prepare a separate, complete Notice of Intent for each such area.

It is the DOL's policy that no information affecting the panel review process will be solicited or accepted past the regulatory postmarked or hand delivered deadlines (see Part V, Use of Panel Review Procedure, below). All information provided before the deadline must be in writing.

IV. Preferential Hierarchy for Determining Designations

In cases in which only one organization is applying for a clearly identified geographic area and the organization meets the requirements at 20 CFR 632.10(b) and 632.11(d), DOL shall designate the applying organization as the grantee for the area. In cases in which two or more organizations apply for the same or an overlapping area, DOL will utilize the order of designation preference described in the hierarchy below. The organization which falls into the highest category of preference will be

designated, assuming all other requirements are met. The preferential hierarchy is:

(1) *Indian tribes, bands, or groups on Federal or State reservations for their reservation; Oklahoma Indians (see Part VII, Special Designation Situations, below); and Alaskan Native entities (see Part VII, Special Designation Situations, below).*

(2) *Native American-controlled, community-based organizations with significant support from other Native American-controlled organizations within the community for their existing DOL designated service area and all non-incumbent Native American-controlled, community-based organizations that are challenging such incumbents or seeking to serve areas for which the incumbent is not re-applying.* Non-incumbent organizations must submit evidence of significant support from other Native American-controlled organizations within the community.

Competition shall occur only when a non-incumbent can demonstrate in its application, by verifiable information, that it is potentially significantly superior overall to the incumbent. Such potential will be determined by the consideration of such factors as the following: completeness of the application; documentation of past experience and Native American-controlled organizational support; and the capability of the incumbent. In the instance of no incumbent, new applicants qualified for this category would compete against each other.

(3) *Organizations (private nonprofit or units of State or local government) having a significant Native American advisory process, such as a governing body chaired by a Native American and having a majority membership of Native Americans.*

(4) *Non-Native American-controlled organizations without a Native American advisory process.* In the event such an organization is designated, it must subsequently develop a Native American advisory process.

The Chief, DINAP, may convene a task force to assist in making hierarchal determinations. The task force also may perform such technical and advisory functions as determining which areas have more than one applicant for designation, documenting the eligibility of new applicants, and ascertaining the timeliness of final Notice of Intent submissions. The role of the task force is that of a technical advisory body.

The Chief, DINAP, will ultimately advise the Grant Officer in reference to which position an organization holds in the hierarchy. Within the regulatory time constraints of the designation process, the Chief, DINAP will utilize whatever information is available.

The applying organization must supply sufficient information to permit the determination to be made. Organizations must indicate the category which they assume is appropriate and must adequately support that assertion. As indicated earlier, applicants will not be able to provide any information past the January 1 postmark on hand delivered deadlines, and no information will be solicited by DINAP.

V. Use of Panel Review Procedure

Competition may occur under the following circumstances:

(1) The Chief, DINAP, advises that a new applicant qualified for the second category of the hierarchy appears to be potentially significantly superior overall to an incumbent Native American-controlled, community-based organization with significant local Native American community support.

(2) The Chief, DINAP, advises that more than one new applicant is qualified for the second category of the hierarchy, and the incumbent grantee has not re-applied for designation.

(3) The Chief, DINAP, advises that two or more organizations have equal status in the third or fourth categories of the hierarchy.

When competition occurs, the Grant Officer may convene a review panel of Federal officials to score the information submitted with the Notice of Intent. The purpose of the panel is to evaluate an organization's capability, based on its application, to serve the area in question. The panel will be provided only the information described at 20 CFR 632.11 and submitted with the final Notice of Intent. The panel results will be advisory to the Grant Officer, not binding. In reviewing information submitted by the organization, the panel will not accept simple assertions. Any information must be supported by adequate and verifiable documentation.

The factors listed below will be considered in evaluating the capability of the applicant. In developing the Notice of Intent, the applicant should organize his documentation of capability to correspond with these factors.

(1) Operational Capability—40 points (20 CFR 632.10 and 632.11).

(i) Previous experience in successfully operating an employment and training program serving Indians or other Native Americans of a scope comparable to that which the organization would operate if designated—20 points.

(ii) Previous experience in operating other human resouces development programs serving Indians or other Native Americans or coordinating employment and training services with such programs—10 points.

(iii) Ability to maintain continuity of services to Indian or other Native American participants with those previously provided under JTPA—10 points.

(2) Applicant's Understanding and Program Approach to Fulfilling the Training and Employment Objectives of JTPA Section 401—20 points. (20 CFR 632.2).

(3) Planning Process—20 points. (20 CFR 632.11).

(i) Private sector involvement—10 points.

(ii) Community support as defined below in Part VIII, *Designation Process Glossary*—10 points.

(4) Administrative Capability—20 points. (20 CFR 632.11).

(i) Previous experience in administering public funds under DOL or similar administrative requirements—15 points.

(ii) Experience of senior management staff to be responsible for DOL grant, if designated—5 points.

VI. Notification of Designation/ Nondesignation:

The Grant Officer will make the final designation decision giving consideration to the following factors: the review panel's recommendation, in those instances in which a panel is convened; input from DINAP, OSTP, the Office of Financial and Administrative Management, and the Office of the Inspector General; and any other available information regarding the organization's responsibility. The Grant Officer's decisions will be provided to all applicants by March 1, as follows:

(1) *Designation Letter.* The designation letter signed by the Grant Officer will serve as official notice of an organization's designation. The letter will include the service area for which the designation is made. It should be noted that the Grant Officer is not required to adhere to the geographic area requested in the final Notice of Intent. The Grant Officer may make the designation applicable to all of the area required, a portion of the area requested, or, if acceptable to the designee, more than the area requested.

(2) *Conditional Designation Letter.* Conditional designations will include the nature of the conditions, the actions required to be finally designated and the time frame for such actions to be accomplished.

(3) *Non-designation Letter.* Any organization not designated, in whole or in part, for an area requested will be

notified formally of the non-designation and given the basic reasons for the determination. An applicant for designation that is refused such designation, in whole or in part, may file a Petition for Reconsideration in accordance with 20 CFR 632.13. If an area is not designated for service through the foregoing process, alterantive arrangements for service will be made in accordance with 20 CFR 632.12.

VII. Special Designation Situations

(1) Alaskan Native Entities

DOL has established service areas for Alaskan Native employment and training programs based on the following: the boundaries of the regions defined in the Alaska Native Claims Settlement Act (ANCSA); the boundaries of major subregional areas where the primary provider of human resource development and related services is an Indian Reorganization Act (IRA)-recognized tribal council; and the boundaries of the Federal reservation in the State. Within these established service areas, DOL has designated the primary Alaskan Native-controlled human resource development services provider or an entity formally designated by such provider. These entities have been regional nonprofit corporations, associated corporations established by the regional nonprofit corporation, IRA-recognized tribal councils and the tribal government of the Metlakatla Indian Community. DOL intends to follow these principles in designating Native American grantees in Alaska for Program Years 1989–1990.

(2) Oklahoma Indians

DOL has established a service delivery system for Indian employment and training programs in Oklahoma based on a preference for Oklahoma Indians to serve portions of the State. Generally, service areas have been designated geographically as countrywide areas. In cases in which a significant portion of the land area of an individual county lies within the traditional jurisdiction of more than one tribal government, the service area has been subdivided to a certain extent on the basis of tribal identification information in the most recent Federal Decennial Census of Population. However, in cases in which members of many different tribes reside in a given county, no attempt has been made to apportion those members among all of the respective tribes. Wherever possible, arrangements mutually satisfactory to grantees in adjoining or overlapping service areas have been honored by DOL. DOL intends to follow these principles in designating Native American grantees in Oklahoma for Program Years 1989 and 1990 to preserve continuity and prevent unnecessary fragmentation.

VIII. Designation Process Glossary:

In order to ensure that all interested parties have the same understanding of the process, the following definitions are provided:

(1) Indian or Native American-Controlled Organization

This is defined as any organization with a governing board, more than 50 percent of whose members are Indian or other Native American people. Such an organization can be a tribal government, Native Alaskan or Native Hawaii entity, consortium, or public or private non-profit agency. The governing board must have decision making authority for the section 401 program.

(2) Service Area

This is defined as the geographic area described as States, counties, and/or reservations for which a designation is made. In some cases, it will also show the specific population to be served. The service area is defined finally by the Grant Officer in the formal designation letter. Grantees must ensure that all eligible population members have equitable access to employment and training services within the service area.

(3) Established Service Area

This is the area defined by geography or service population which DOL has previously designated as a service area for Indian and other Native American JTPA purposes.

(4) Community Support

This is evidence of active participation and/or endorsement from Indian or other Native American-controlled organizations within the geographic area for which designation is requested. Applicants should provide supporting documentation regarding the nature of such organizations, e.g., evidence of Indian and other Native American control, articles of incorporation or charter, size, membership, etc.

While applicants are not precluded from submitting attestations of support from individuals, the business community, State and local government offices, and community organizations that are not Indian or other Native American-controlled, they should be aware that such endorsements do not meet DOL's definitional critical for community support.

Signed at Washington, DC, this 4th day of August, 1988.

Paul A. Mayrand,

Director, Office of Special Targeted Programs.

Herbert Fellman,

Chief, Division of Indian and Native American Programs.

Robert D. Parker,

Grant Officer, Office of Grants and Contracts Management.

Roberts T. Jones,

Acting Assistant Secretary of Employment and Training.

[FR Doc. 88–18231 Filed 8–11–88; 8:45 am]

BILLING CODE 4510-30-M

Review Panel for the Job Training Partnership Act (JTPA) Presidential Awards; Renewal

In accordance with the provisions of the Federal Advisory Committee Act, and after consultation with the General Services Administration, the Secretary of Labor has determined that the renewal of the Review Panel for the JTPA Presidential Awards is in public interest in connection with the performance of duties imposed on the Department by section 172 of the Job Training Partnership Act.

The Panel will advise the Secretary of Labor on the selection of the Presiential Awards recipients. The Panel will perform an expert review of the nominations for each of the four award categories and will provide the Secretary with its views and recommendations on the top nominations.

The Panel will consist of training and employment experts representing the private sector, labor, private industry councils, community-based organizations and Federal, State, and local governments. Other than the Federal Government members, the members shall not be compensated and shall not be deemed to be employees of the United States.

The Panel will function solely as an advisory body and in compliance with the provisions on the Federal Advisory Committee Act. Its charter will be filed under the Act 15 days from the date of this publication.

Interested persons are invited to submit comments regarding the renewal of the Review Panel for the JTPA Presidential Awards. Such comments should be addressed to: Mr. Robert N. Colombo, Director, Office of Employment and Training Programs, U.S. Department of Labor, ETA, 200 Constitution Avenue NW., Room N–

4469, Washington. DC 20210, Telephone: (202) 535-0577.

Signed at Washington DC, this 8th day of Aug. 1988.

Ann McLaughlin,

Secretary of Labor.

[FR Doc. 88-18228 Filed 8-11-88; 8:45 am]

BILLING CODE 4510-30-M

Job Training Partnership Act; Review of Experience

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice; request for comments..

SUMMARY: The Employment and Training Administration of the Department of Labor is conducting a review of experience under the Job Training Partnershp Act and is requesting interested parties to submit written comments on issues related to the future quality and effectiveness of the program.

DATE: Written comments on the issues discussed in this notice shall be submitted by mail, postmarked no later than September 26, 1988.

ADDRESS: Send written comments to: Roberts T. Jones, Acting Assistant Secretary, Employment and Training Administration, Room S2308, 200 Constitution Avene, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Lloyd Feldman, Director, Division of Planning, Policy, and Legislation, Office of Strategic Planning and Policy Development, Employment and Training Administration, Room N5636, 200 Constitution Avenue NW., Washington, DC 20210. Telephone: (202) 535-0664 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Since the enactment of the Manpower Development and Training Act more than a quarter century ago, the United States Government has pursued a policy of active intervention in the labor market through employment and training programs. During the ensuing years, the Nation's employment and training system has evolved through a succession of basic authorizing statutes and amendments e.g., the Comprehensive Employment and Training Act (CETA).

On October 13, 1982, President Reagan signed into law the Job Training Partnership Act (JTPA), the most recent legislative expression of the Nation's job training policy. As in the case of earlier employment and training legislation, the drafters of JTPA sought to build upon past experience, retaining features that had proven effective and modifying or eliminating those that appeared to limit program effectiveness.

The following basic features of JTPA represented major changes in the organization of the program:

- A shift in responsibility for program management from the federal to the State and local governments.
- The assignment of a substantive role to the private sector in the planning and oversight of the program.
- An emphasis on training and related services for participants with a consequent deemphasis on using the program to provide income maintenance or subsidized employment.
- The establishment of performance standards as a key operational component of the program.
- Inclusion of machinery to increase the coordination of employment and training with other human services at the state and local levels.
- Emphasis on services for youth.

With the completion, this year, of five years of operational experience, it was felt that the program had matured sufficiently and patterns of service and performance had been clearly enough established that it would be timely to take stock of the experience to date and to analyze the basic policy issues which must be addressed in charting the future course of JTPA.

Accordingly, DOL has decided to conduct a public review of the JTPA program with an interim report planned for January 1989.

The review will focus primarily on services for economically disadvantaged youth and adults under Titles I and II-A of the Act. However, the scope of the review will include services for dislocated worker (Title III), and disadvantaged youth enrolled in the summer employment program (Title II-B). Activities under Title IV, particularly Indian and Native American programs, will also be considered, where the issues addressed are relevant to these programs.

The ultimate objective of the review will be to enhance the quality of services provided to JTPA enrollees and to explore the potential of the JTPA system to serve as a building block for a comprehensive human resource delivery system. While the results of the review may have implications for the roles of the Federal Government, the States, locally-elected officials and Private Industry Councils (PICs) in Service Delivery Areas (SDAs), the basic relationship of the partners in the delivery system will not be a subject of the review.

The purpose of this notice is to identify the specific issues which will form the core of the agenda for this review. A JTPA Advisory Committee, comprised of representatives of the JTPA system, public interest groups, community organizations, business, labor, education, veterans, and the general public will address and provide advice on these issues. The issues will also form the basis for discussion and comment at meetings held at the State and local levels. The general public will be given an opportunity to react to the issues as a result of publication of this announcement in the **Federal Register.**

Experience Under The Program

Since the program became operational in 1983, approximately 5 million persons have received services under JTPA, not including youth enrolled in the Summer Youth Employment Program (SYEP). Of these, about 90 percent were served under the two programs administered at the State and local level: Title II-A which provides grants to States and local areas to support locally administered training and employment programs and Title III which provides funds to States to address problems of workers dislocation resulting from plant closings and mass layoffs.

Title II-A Grants to States and Local Areas

Participant Characteristics. This title was intended primarily to serve the economically disadvantaged and that trust is reflected in the characteristics of the participants. Thus, the Act's requirement that at least 90 percent of Title II-A participants be economically disadvantaged was exceeded (93 percent in Program Year (PY) 1986 (July 1, 1986—June 30, 1987)).

In PY 1986, some 44 percent of the participants in Title II-A were under 22 years of age; the Act requires that at least 40 percent of the funds be used for youth. Approximately 52 percent of the participants were female and 50 to 56 percent were high school graduates, while 27 percent were dropouts and 17 percent were still in school.

On the basis of most characteristics for which data are available, persons, enrolled in the program are representative of the eligible population and these data suggest that the program is targeting those in need. Thus, some 22 percent of the program participants in PY 1986 were Aid to Families with Dependent, Children (AFDC) recipients as compared to 17 percent of the eligible population. Minorities made up half of the enrollment as compared to 39 percent of the eligible population. The percentage of youth enrolled is twice their proportion of the eligible population. However, the education

level of enrollees, while not a perfect measure of competence, does suggest that the program has enrolled those disadvantaged persons with a better prognosis for success than the eligible population. Approximately 56 percent of all participants—and 73 percent of adults—were high school graduates, compared to 49 percent of the eligible population. Also, Hispanics—a group that has sufferd serious labor market problems—constituted ten percent of JTPA enrollment, but 13 percent of those eligible for the program.

Service Proved. In PY 1986, 36 percent of the Title II-A participants were in classroom training, 22 percent in on-the-job training (OJT), 19 percent in job search assistance, 9 percent in work experience, and 14 percent in "other" services (*e.g.*, counseling and testing). The distribution of participants among these services tends to vary depending on their characteristics. For example, makes, older enrollees and the better educated tend to be found disproportionately in OJT; youth and minorities tend to be over represented in work experience activities. The median length of stay varies widely among the various kinds of services, from almost 20 weeks for classroom training to 14 weeks for participants in OJT and less than 4 weeks in job search assistance. The average length of stay in the program was 18 weeks.

Under JTPA there appears to have been a marked shift toward activities geared to more immediate and direct placement, such as job search assistance. Together, job search assistance and "other" services account for about one-third of the JTPA enrollment as compared to the less than 10 percent of CETA participants who received direct referral and "other" in services. Approximately 22 percent of JTPA enrollees are in OJT programs—about double the rate under CETA.

Program Outcomes. Of those terminationg from Title II-A during PY 1986, 62 percent entered employment. Entered employment rates tended to be higher for males (65 percent), high school graduates (71 percent) and lower for black participants (56 percent) and welfare recipients (54 percent). Among the various program activities, the entered employment rate ranged from 77 percent for job search assistance and OJT to 46 percent for work experience. The rate for classrooms training was 52 percent.

The average hourly wage for those entering employment was $4.72. Wage rates were notably higher for males ($5.04), those with some post high school education ($5.30) and lower for females ($4.49), black participants ($4.55), and welfare recipents ($4.57). By service provided, the highest average hourly rate was achieved by those who were in classroom training ($5.03), followed by terminees from OJT ($4.87), job search assistance ($4.68), and participants in work experience ($4.16). The overall placement rate under JTPA compares very favorably with that achieved under the earlier CETA program; about two-thirds of JTPA terminees placed as compared to one-third under the earlier program. (Data on retention following placement are not available). However, hourly wages for those placed in jobs have increased only marginally over those achieved in the preceding program some eight years earlier; if adjusted for inflation, the average hourly wage is actually lower.

Role of the Private Sector—One of the principal changes under JTPA was the substantive role provided for the private sector in planning and administering training and employment programs at the local level through the creation of private industry councils in each designated service delivery area. Currently, there are over 620 PICs, with some 16,000 members, including an estimated 9,000 representatives of the business sector.

Title III Dislocated Worker Program

Participant Characteristics. Since Title III focuses on experienced workers, the characteristics of participants in the program are distinctly different from those of Title II-A enrollees. Thus, in PY 1986, only 4 percent of workers enrolled in Title III were under 22 years old (as compared to 44 percent of Title II-A participants), while almost 90 percent were betwen the ages of 22 and 54. Similarly, only one-third of Title III participants were economically disadvantaged compared to over 90 percent of those in the Title II program.

Dislocated worker program participants tend to be relatively well educated with over 80 percent having at least a high school education. Reflecting the eligible population of dislocated workers, enrollment in title III is predominately male (65 percent). Minorities account for 23 percent of the participants as compared to 19 percent of eligible dislocated workers.

Services Provided. Under the the dislocated worker program, the primary service provided is job search assistance with half of the participants enrolled in this activity. Classroom training accounts for 26 percent of the enrollees, OJT for 12 percent and "other" services for 12 percent. The characteristic of participants in the various service components are fairly similar. The average length of stay in the title III program is 20 weeks but varies by service provided with the longest duration in classroom training at 23 weeks, followed by about 15 weeks for both OJT and job search assistance.

Program Outcomes. Of some 140,000 participants who terminated for Title III dislocated worker programs in PY 1986, 69 percent entered employment. The entered employment rate tended to be higher for males (74 percent) than for females (64 percent), black participants (60 percent) and welfare recipients (45 percent). Entered employment rates were particularly high for those who had been in OJT programs (89 percent).

The average hourly wage rate for terminees from Title III programs entering employment was $6.36. The rate was highest for those terminating from classroom training and job search assistance. Terminees from OJT had the lowest hourly wage rate.

Issues For The Future

The general objective of this review of JTPA is to determine how the quality and effectiveness of the program can be enhanced and how the program can help in building a coherent local human resource delivery system. In carrying out the review, four general areas of inquiry will be pursued:

- Whom should the program serve?
- What services should be provided and how can the quality of services be improved?
- How can the management tools used in the program be enhanced?
- Should JTPA be coordinated more closely with non-JTPA services and serve other national priorities? Should the public-private partnership under JTPA be broadened?

The key issues in these areas of inquiry, briefly discussed below, will be included in the review process. Public comment is particularly invited on these issues. However, comments on related JTPA subjects, which may not be specifically embraced by these subject areas, may also be submitted.

Whom Should the Program Serve?

Eligibility for the Program and Targeting Policy. Eligibility for Title II-A of JTPA is generally limited to those who are economically disadvantaged, *i.e.*, who meet income criteria issued by DOL. Up to 10 percent of the participants need not meet these income criteria if they have encountered barriers to employment. Title II-A also requires that not less than 40 percent of each SDA's funds be spent on youth, and that school dropouts and AFDC recipients be served on an "equitable basis."

The limited resources available for JTPA programs cannot meet the needs of the entire eligible population. Estimates of the number of disadvantaged youth and adults eligible under the income criteria approach 40 million. Therefore, of necessity, a priority for service must be established among these who are eligible. Within the parameters of the law, eligibility determination is a local decision. JTPA directs SDAs to provide employment and training opportunities to those who can benefit from, and are most in need of, such opportunities and to make efforts to provide equitable services among substantial segments of the eligible population.

Compared to the eligible population, Title II–A programs have served a higher proportion of blacks, youth and AFDC recipients. However, the programs have served a lower proportion of Hispanics and those with less than high school degree. The JTPA system has been criticized for failing to serve those most in need. It has been argued that SDAs tend to focus short-term services on job ready individuals in order to achieve high placement rates with low unit costs and thereby achieve "success." For example, it has been noted that the cost per placement for youth is less than half the national standard. It has been suggested that, with a limited amount of dollars, SDAs may choose to serve the largest possible number of eligible individuals by serving those that can be served at relatively low cost. Performance standards are often cited as the reason for JTPA not serving a more at-risk population. However, national JTPA performance standards allow for local flexibility. They can be adjusted by Governors to reflect client characteristics and local economic conditions. SDAs may also request further adjustment for those with more serious employability problems. Others have taken the position that good management dictates that, within the eligible population, those selected for service should have the best prognosis for success.

The basic policy issue posed is who, within the economically disadvantaged population, should be served under JTPA?

• Should the program serve those disadvantaged individuals who face the most serious barriers to employment because of inadequate basic skills, poor orientation to the demands of the workplace, physical or mental disabilities, and related problems? Or, should the program enroll those individuals who meet the law's income test but are best equipped in terms of education and attitude toward work to succeed in competitive employment?

• What are the best measures of at-risk status or serious barriers to employment? Do they vary from group to group?

• A policy decision on targeting has implications for the services to be provided. Serving those who are most disadvantaged in terms of verbal, quantitative and analytic skills as well as exposure to the discipline of the workplace will require a broader range of services than serving those who are more job ready. What is the optimum range and mix of services which should be provided for these individual subgroups of the disadvantaged population?

• Targeting policy choices will also have cost implications. The broader range of services required to achieve the employability of the most disadvantaged will result in high unit costs—and fewer persons served at a given budget level—than will the lower unit costs associated with serving the least disadvantaged. What are the costs of serving various disadvantaged subgroups? How many individuals should be served at a given budget level?

• What are the benefits and relative return on investment to society in serving various subgroups of the disadvantaged population?

• Policy decisions concerning who is to be served will also have implications for the outcomes which can be anticipated for those participating in the program. A basic issue is the nature of the outcome, itself. Under JTPA, the outcome anticipated for participants is increased employment and earnings and reduced welfare dependency. An alternative—particularly for those subgroups with low basic skill levels—is to establish increased competency levels as an acceptable outcome. In either case, the level of success which can be anticipated will be lower for those with more disadvantaged backgrounds. For example, in PY 1986, of those Title II–A enrollees who were high school graduates, approximately 71% were placed in jobs whereas only 57% of those who were high school dropouts entered employment following the program. High school graduates were placed in jobs paying $4.88 an hour; dropouts' wages at placement were $4.52. What outcome measures should be used for various subgroups of the population and what outcome levels should be anticipated for these subgroups?

What changes should be made in performance standards to assure that these outcomes are adequately reflected?

• In carrying out any changes in policy with respect to who is to be served, what changes—if any—should be made in the law's eligibility requirements and targeting provisions for youth, school dropouts and AFDC recipients?

• Should the Act's provisions allowing up to ten percent of participants to be non-disadvantaged individuals who encounter barriers to employment be revised?

• What non-legislative, administration measures should be taken to implement changes in eligibility/targeting policies?

• Under either current or changed eligibility requirements, what criteria should be used at the operational level to select clients for the program?

Allocation Formula. Closely related to the issue of eligibility for the program and targeting policy is the question of the adequacy of the formula used to allocate funds Title II–A. If a change in eligibility/targeting policy is made, consideration should also be given to related changes in the allocation formula. However, even under current policy, questions have been raised about the adequacy of the present formula.

Currently, the formula allocates funds to States using three factors: One-third based on the relative number of individuals residing in areas of substantial unemployment (over 6½ percent unemployed); one-third based on the relative excess number of unemployed (unemployed over 4½ percent); and one-third based on the relative number of economically disadvantaged individuals. The same formula is used to allocate Title II–B (Summer Youth Program) funds, and to distribute State funds under both programs to the local level. The Administration has proposed legislation that would revise the Title II–B allocation formula to better target resources to the population served by that program. The new formula would allocate funds based on the relative number of disadvantaged youth residing in each State and Service Delivery Area.

In recent years, at congressional hearings and elsewhere, concerns have been raised that the JTPA allocation formula does not sufficiently direct resources to where the eligible population is located. The current formula targets resources heavily to areas with high adult unemployment. Unemployment data have been used for allocating employment and training funds because they provide one measure of relative economic hardship and are

available on a current basis. However, since many urban SDAs contain both pockets of extreme poverty an very affluent areas with vigorous economies, employment conditions in these areas may not be the best indicators of their relative need for resources for poor youth and adults. Moreover, cyclical changes in the economy may cause large funding swings under the current formula that may be unrelated to the poverty situation in a local area. Research sponsored by DOL has confirmed that the Title II-A allocation formula does not distribute resources in a fully equitable manner. In particular, it was found that some regions of the country and central cities, where the economically disadvantaged population is heavily concentrated, receive a smaller share of State and local funding than their share of the eligible population would dictate.

A serious information problem complicating this issue is the lack of current data on the relative number of economically disadvantaged individuals in SDAs. Currently, the decennial census is the only available source for these data. With the passage of time, these data become less reflective of the distribution of low income individuals. On the other hand, collection of these data on a more frequent basis would be extremely costly.

The basic issue is whether the Title II-A allocation formula should be changed to more accurately reflect the law's eligibility provisions, either under the current statute or under new, revised eligibility criteria.

• Should any of the current factors—economically disadvantaged, excess unemployment, or unemployment in areas of substantial unemployment—be eliminated?

• Should any of these factors be modified? Should different weights be assigned to these factors?

• Should new factors be added to the formula and, if so, which ones and what data sources should be used?

• If the present factors are retained, should the data currently used to measure the relative number of economically disadvantaged individuals in SDAs be updated? How can this best be achieved and what would be the cost of an alternative to the current use of decennial census data, such as more frequent surveys?

• Should the delivery and funding of services to youth and adults be separated in the legislation with different funding allocation formulas developed for each group?

What Services Should be Provided and How can the Quality of Services be Improved?

Nature and Quality of Services Provided. The law gives SDAs broad discretion in determining the range and mix of services to be provided to enrollees. A variety of factors enter into SDAs' decisions on the mix and duration of services selected. An important consideration is the nature of the clientele to be served. More disadvantaged individuals generally require more comprehensive services, over a longer period of time, at higher costs, to become employable than do the less disadvantaged.

A second consideration is the occupational objective of a training program; higher level skills usually require longer-term training. More intensive remediation usually requires longer-term training as well. A third factor is the total number of clients to be served. With finite resources available, serving a larger number of enrollees in an SDA will reduce the unit cost—and possibly, the quality—of training provided to individuals. Local decisions on the services to be provided also must rely on the availability of adequate service deliverers. Finally, the existence of the performance standards system has influenced local service strategies although the extent of that influence has been subject to debate.

It has been argued that many SDAs have opted for short duration programs, geared to the least disadvantaged, resulting in maximum enrollment and high placement rates.

The average length of stay in Title II-A in FY 1986 was 18 weeks. It has been contended that programs of 4-5 months duration allow insufficient time to prepare the truly disadvantaged for stable employment at good wage levels.

Others have taken the position that changes under JTPA—emphasis on performance standards, the removal of training allowances; and the influence of the PICs—have all contributed to increased program efficiency under JTPA, thus enabling SDAs to achieve more cost-effective service, during shorter training periods, than was possible under earlier legislation.

In either case, if JTPA is to focus its services on the most disadvantaged members of the eligible population, it can be argued that the program should be limited to basic skills and literacy training. Under this approach, specific occupational skills training would be the responsibility of public and private vocational schools and employers.

Conclusive evidence about the quality of JTPA services is lacking. Duration of training is only a rough proxy for program quality. However, the available data do suggest that there may be some grounds for concern about the services currently being provided. Only one-third of Title II-A enrollees receive classroom training, generally the most substantive service area under JTPA. A larger proportion of enrollees—more than half—receive either on-the-job training or low-cost job search assistance and related services. In general, the low cost per placement under Title II-A suggests that service quality may be less than optimal in many SDAs. The cost per placement has been well below the performance standard level: $2,905 for adults in FY 1986 ($4,374 standard). The cost per positive termination was $2,308 for youth ($4,900 standard).

The central issue to be addressed is whether changes are needed in the nature, mix and quality of services provided under JTPA.

• A key element of this question is whether JTPA should continue to attempt to provide participants with specific occupational skills or should the program focus on remediation, meeting the basic skills deficiencies of enrollees in reading, writing, mathematics and orientation to the workplace. This question particularly arises if a policy of reaching the most disadvantaged is pursued.

• If a policy of remediation is to be pursued, should changes be made in the nature of the outcomes anticipated and the associated performance standards?

• For example, increased levels of basic skills competency, rather than or in addition to placement, may become a more appropriate objective for the program.

• Whether a program emphasis on either remediation or on specific skills training is elected, the policy on eligibility and targeting will have implications for the range and cost of the services to be provided. As noted earlier, a decision to serve the most disadvantaged will require a broader and more costly range of services than will be the case for those in the eligible population who are best equipped for the job market. What primary and supportive services should be provided—and at what cost—to support a policy of serving the most seriously disadvantaged and assuring their eventual placement in stable, well-paid employment?

• What are the best measures of "quality" training—duration, competency-based, individually tailored, self-paced?

• Should the Act's restrictions on the amount of funds which can be used for

supportive services be revised? Should the restriction be relaxed generally or only for specific subgroups in the eligible population? And, if it is to be limited to the latter, how should the eligible subgroup be defined?

• What policy and program approaches should be followed at the Federal, State and local levels to effect changes in the services provided to enrollees: Legislative changes; policy leadership; technical assistance; modification of performance standards and the adjustment models; other courses of action?

Payment of Stipends, Allowances and Bonuses. Within the general area of services improvement, concern has been expressed about JTPA's current strict limits on the payment of stipends, allowances or bonuses. The restrictions were included in the law because of a perception that, under previous programs, individuals enrolled in order to receive training allowances and stipends, rather than to increase their employability. It was also felt that participants under JTPA would have other sources of financial support while in the program: Unemployment insurance; AFDC and other welfare benefits; and, in the case of youth, financial assistance from their families.

The law states that not more than 30 percent of each SDA's funds may be spent for the combined costs of administration and supportive services. The latter category includes expenditures for needs-based payments. Because there is a separate limit of 15 percent on administrative costs, this effectively places a limit of 15 percent on the needs-based payment/supportive service cost category. The act allows a waiver of the supportive services cost limitations if specified conditions in a local area are met.

The expenditure rates for supportive services have remained essentially the same since the implementation of JTPA: 11 percent for participant support, including needs-based payments. However, the actual figure may be higher since the cost of some supportive services are charged to "training" under performance-based contracts. While national data are not collected on requests for waivers of the cost limitations, it appears that few requests for such waivers have been filed.

If it is decided to target the program on the hardest-to-serve, there is concern that these "at-risk" individuals will not be able, or willing, to participate in JTPA programs unless stipends and allowances are available to help them with living expenses while they are in training.

Thus, it has been suggested that some liberalization of the restrictions on allowances, stipends and bonus payments is desirable. On the other hand, relaxing these restrictions means that funds may be diverted from training to pay for income support. An indirect consequence could be fewer persons served.

The basic issue is whether JTPA enrollees should receive stipends or allowances while enrolled in the program.

• It had been assumed that individuals enrolled in Title II-A and Title III programs would receive sufficient financial support from non-JTPA sources to allow them to enter and complete the program. Has this been the case? Or are there JTPA-eligible groups which have been discouraged from participating because they lack financial support from non-JTPA sources? Has the lack of financial support for participants forced program planners to shorten the length of training and precipitated higher-than-anticipated dropout rates from the program?

• If a policy decision is made to serve more severely disadvantaged clientele, should the current restrictions on payment of stipends and allowances be revised? If so, should payments be made to all participants or only those who can demonstrate financial need?

• What stipend/allowance levels should be established that would be high enough to provide financial support but not draw individuals into the program in order to receive the allowances?

• If the prohibition against stipends and allowances is retained, should the waiver provisions for supportive services/need-based payments be relaxed?

• Should a system of bonus payments be established which would reward participants for achieving specific levels of competency in the program?

Performance Standards. JTPA requires that the Secretary of Labor establish performance standards for each two-year program planning cycle. These performance standards are the centerpiece of JTPA's performance management system and are designed to assure that the Act's objectives are being carried out at the State and SDA levels.

The measures to be used in PY 1988 and 1989 include several that have been used since the beginning of JTPA. Those measures are the entered employment rates for adults, youth and welfare recipients, the average wage at placement, the youth positive termination rate, the cost per entered employment for adults and the cost per positive termination for youth.

For the first time since JTPA's inception, five new performance measures were introduced for PY 1988 and 1989 to reflect prospective labor markets, recent program experience, rising skill requirements and to more closely relate performance standards to the basic objectives of the Act—increased employment and earnings of enrollees and reduced welfare dependency.

Three policy goals guided these performance standards revisions:

• To encourage increased service to individuals at risk of chronic unemployment, especially youth;

• To foster training investments which lead to long-term employability; and

• To increase basic skills and occupational competency-based training for youth.

Since success in the labor market is directly related to basic skills attainment, a new measure of employability enhancement was added to the youth measure. This new youth measure emphasizes helping youth obtain competencies in basic education and job specific skills to meet the requirements of a rapidly changing workplace.

To foster long-term employability development, DOL introduced four new measures of long-term performance focusing on the employment, earnings and job retention of participants 13 weeks after termination.

Governors have the authority to make adjustments to national standards for each SDA to reflect both local economic conditions and special problems addressed by State policy or local programs. The Department provides an adjustment model to assist Governors and, within prescribed parameters, allows Governors to develop their own methods for adjusting standards to meet local conditions. However, few States have made more than minimal adjustments. Most SDAs have also accepted performance standards prescribed by the States and assigned them to service providers with no adjustments for the type of participants served or the services provided.

DOL has increased the Governors' flexibility by allowing the Governors to chose eight of 12 performance standards to be used in judging SDA performance for the period, PY 1988–1989, July 1, 1988–July 30, 1990. Based on past experience, some express concern about whether Governors will take full advantage of this flexibility to align State goals and performance standards

or whether performance standards will continue to be applied on a largely mechanical basis. Others question whether SDAs will take advantage of the flexibility to adjust standards based on the types of people served or special program services provided, or continue across-the-board upward adjustments of SDA-established performance standards for local service providers to ensure that the SDAs exceed standards.

Concern has also been expressed about the Governors' limited use of their incentive grant authority under the Act's "six percent set-aside" provisions that emphasize rewarding SDAs' performance for exceeding standards. In general, the States have not fully used those provisions to achieve State goals in such areas as client targeting. Rewards can be—but are not typically—given to SDAs which serve particularly at-risk participants.

There are two basic issues which should be addressed with respect to performance standards: the standards themselves and the management of the performance standards system. As has been discussed in this notice, major policy changes with respect to the groups to be served under the program have implications for the nature and level of the standards which should measure performance.

On the management side, the general policy issue raised is whether the Federal Government should be more active in assuring that the States and SDAs make more flexible and creative use of performance standards to achieve State and local policy objectives.

- Should States be better informed by the Federal Government about their current flexibility in using incentive funds/additional standards to better achieve State goals in such areas as client targeting or quality training?
- Are the current statutory outcomes—emphasizing placements, retention, and costs—appropriate if JTPA is to serve a more disadvantaged population?
- Would, for example, a measure of employability enhancement be more appropriate for adults? Should there be other employability enhancements beyond current statutory outcomes for youth—for example, learning gains or return to school for recent school dropouts?
- Should there be a Federal definition of youth employment competency?
- Should there be other statutory outcomes for dislocated workers' programs beyond placement and retention in unsubsidized employment?
- Should the States be given greater authority to use six percent set-aisde incentive funds to reward improvements in program quality, performance, and management?
- Should the Federal Government provide more policy direction and technical assistance on how performance standards are to be utilized and how adjustments can be made?
- Should the Federal Government be given greater authority to collect programmatic and performance data to improve national performance measures?
- Should the States be given greater authority to use the technical assistance portion of the six percent set-aside for post-program data collection and program evaluation?

How Can the Management Tools in the Program Be Enhanced?

JTPA provided for a basic redeployment of responsibility for the job training program among the Federal, State and local governments and business community. The past five years has been a period of adjustment to these new roles.

This has been an ongoing process. Until 1986, for example, Federal management had been restricted largely to: Publishing regulations; making allotments to the States; establishing a performance-based management system; monitoring compliance with the Act; and preparing an annual report to Congress. In 1986, the Department established a "proactive partnership" with the States. This has included a procedure for DOL to provide policy guidance to the States, a management review process to assist States in identifying problem areas, revisions in the performance management system, and limited technical assistance.

The Governor has continued to retain primary authority for issuing State policy, designating SDAs, making substate allocations, establishing fiscal standards and coordination criteria, reviewing and approving substate plans, selecting performance standards, establishing incentive and sanction policies, monitoring performance, and enforcing the provisions of the Act. The Governor is also responsible for providing technical assistance to enhance performance at the SDA level.

Operational responsibility is lodged at the SDA level. This includes developing plans, establishing groups targeted for service, selecting and funding service deliverers, and ensuring compliance.

Frequently, concerns about specific program weaknesses under JTPA are coupled with criticisms of the management of the program at the Federal, State, and local levels. While Federal policy guidance has been more forthcoming in recent years, it has been argued that further and more timely guidance from the Federal level would be desirable. Others propose that policy guidance from the Federal level should be buttressed by more aggressive monitoring and enforcement activities. The adequacy of the technical assistance and labor market information provided by the Federal Government to the States and by the States to the SDAs have been cited as areas in which improvement is needed.

This review does not envision changes in the basic relationships within the JTPA delivery system. However, within that structure, a central issue to be addressed is whether action is needed to improve the management of the system by the Federal, State and local government and private sector partners and, if action is needed, in which management areas it should take placer.

- How can the communication of Federal policy guidance to the States and from the States to the SDAs be improved, both in terms of precision and timeliness?
- Should technical assistance services in the program be strengthened? In which specific areas of program management would more technical assistance be helpful?
- Is more rigorous Federal financial and program oversight and enforcement needed and in which management areas?
- Is planning and program design carried out effectively at the SDA level? If not, what are the deficiencies and how can they be remedied?
- Do the States and SDAs currently receive labor market information which is adequate, in quality and timeliness to support effective program planning? If better information is needed, what specific initiatives are needed at the Federal, State and local levels to improve the available information?
- Are there problems of excessive staff turnover at the management and staff levels in SDAs? If so, how can these problems be addressed?
- What changes—if any—should be made in the current system of program data collection and analysis?
- In what ways can the program of Federal research and development and pilot and demonstration projects contribute to increasing the effectiveness of program management at the State and local levels?
- In the area of financial management, should the Federal government provide more detailed guidance in such areas as procurement and contracting practices, including

performance-based contracting, and audit resolution?

Should JTPA be Coordinated More Closely with Non-JTPA Services and Serve Other National Priorities? Should the Public-Private Partnership under JTPA be Broadened?

Coordination. JTPA stresses coordination at the State level and with public and private agencies at the local level. Two statutory State level coordination mechanisms are: (1) Representation of State educational, rehabilitation and public assistance agencies on the State Job Training Coordinating Council—the advisory board to the Governor charged with oversight of JTPA; and (2) the requirement that the States' planning document establish criteria for local and State coordination with other public agencies or programs. In addition, eight percent of total Title II-A funds that flow to a State must be spent, in part, to increase coordination with educational activities.

A number of public agencies and local organizations sit on local Private Industry Councils, since representation from education agencies, rehabilitation agencies, economic development agencies, and community-based organizations is required by law. SDAs can, potentially, coordinate with vocational education programs at the secondary and post-secondary levels, adult education, vocational rehabilitation, welfare agencies, social service and health agencies in a number of ways to provide supplemental or supportive services to JTPA enrollees. Such arrangements are also possible with other DOL-funded programs, such as Job Corps and the Employment Service.

The decentralized nature of JTPA and other education, social service and health programs potentially allows for considerable flexibility at the State and local levels in coordinating separately-funded and administered services for persons with multiple needs. However, operationally, such coordination has been achieved in only a very few SDAs.

DOL has encouraged the JTPA system at the State and local level to coordinate with education, social, health and other human resource programs and agencies as part of a broader effort to enable the JTPA system to serve disadvantaged clients with multiple needs more effectively. For example, DOL and the Department of Health and Human Services are jointly funding projects to demonstrate how job training, education, social, and health services can be effectively combined to address the needs of several target groups such as at risk youth and families dependent on public assistance. DOL and the Department of Education (DOE) are jointly funding projects designed to link DOE-funded literacy activities with job training for various target groups.

Historically, effort have been made to coordinate employment and training programs with human services funded by other Federal agencies. For a variety of reasons—lack of uniformity in funding cycles, variations in eligibility requirements and other factors such as lack of flexibility, incentives and leadership at all levels—these efforts have not proven successful. However, experience gained in recent demonstration projects and the clear intent of Congress as reflected in the language of JTPA and the Carl D. Perkins Vocational Education Act for example, suggest that renewed efforts should be made in this direction.

The central issue to be addressed is whether, in the future, high priority should be assigned to linking services under JTPA with non-JTPA services in order to provide more comprehensive assistance to JTPA clients.

- Which non-JTPA services—particularly those funded by other Federal agencies—should be linked administratively to employment and training programs under Title II-A and III?
- How can JTPA services be coordinated more effectively with economic development programs?
- Which DOL-funded services can be more effectively linked with the Title II-A and III programs; the Employment Service; Job Corps; unemployment insurance; other?
- What are the best and most flexible administrative devices to achieve linkages: *e.g.*, a case manager system; central intake and referral to all services; cross-referral among service agencies; pooling of funds and establishment of a local human resources "super-agency; a combination of these approaches or other approaches?
- Should further coordination of services be achieved through legislative action of administratively?
- If legislative action is desirable, what modifications are needed in other Federal statues which authorize related non-JTPA services?
- If administrative action is appropriate, what types of action at the Federal and State levels can be most effective in helping SDAs and PICs to achieve linkages at the local level: technical assistance; financial incentives; joint policy guidance to the field from DOL and other Federal agencies; other approaches?
- Should States be encouraged to expand the responsibilities and membership of the State Job Training Coordinating Councils with respect to program coordination?

Meeting Other National Priorities. This review assumes that JTPA will retain its basic objectives: Increasing the employment and earnings and reducing welfare dependency among economically disadvantaged and dislocated workers.

However, JTPA—potentially—can serve other national objectives, at the same time. For example, due primarily to demographic factors, the country is beginning to experience labor shortages in specific occupations. These shortages are likely to intensify, at least through the year 2000. Specific U.S. industries will be faced with increasing competitive pressure from abroad. JTPA training could be geared to help address these national problems while also serving JTPA clientele. Training could be targeted to shortage occupations and industries which need trained workers to compete more effectively.

The underlying issue posed here is whether JTPA should continue to be limited to the national objectives currently in the Act or be used to serve other national priorities, particularly in the area of economic policy, as well.

- Are there other national priorities—such as addressing labor shortages and supporting export industries—which can be furthered by the JTPA program and, at the same time, enhance the employment prospects of disadvantaged and disclosed clients? Which additional national goals can best be served by the JTPA program?
- Which approaches should DOL follow to encourage States and SDAs to factor such national objectives into their planning: policy guidance, promotional/education efforts; technical assistance; financial incentives; other approaches?
- Are legislative changes required?

Broadening the Public/Private Partnership. In one form or another, the business community has played a role throughout the history of employment and training programs. However, prior to the enactment of JTPA, that role was limited largely to training a small proportion of program participants in OJT programs.

With JTPA, the public-private partnership became a central feature of the job training program. Through the PICs, business was given substantive, partnership responsibilities for planning, providing policy direction and overseeing local JTPA programs.

However, Congress signaled its intent that the PICs carry out a more extensive

role in the community. In amendments to the Wagner-Peyser Act and the Carl D. Perkins Vocational Education Act, the PIC was given responsibility to review the planning for vocational education and the Employment Service at the local level. In addition, by requiring that the PIC be broadly representative of local human service and economic development agencies, the Congress placed the Councils in a position to extend the public-private partnership to areas other than job training.

At present, the PIC is the only Federally-supported entity at the local level that is both funded to provide a wide range of services and, at the same time, structured to represent business, labor, education and other non-Federal human services partners in the community. This unique combination of program resources and broad organizational leverage at the local level opens up the possibility for broadening the local public-private partnership embodied by the PIC. To date, a number of individual PICs have extended their scope of activity beyond JTPA services and have developed active working relationships with local school systems and social service agencies.

The basic issue to be addressed is whether the public-private partnership represented by the PIC should be extended to encompass other human and related services at the local level.

- Which local human and economic services would benefit most from PIC involvement: Public education; social services; economic development; mental health services; others?
- What role should be envisioned for the PIC in these non-JTPA service areas: Link the services to JTPA activities; help assure coordination among the services generally; provide a business/labor market information perspective; review plans to reduce duplication of services; other functions?
- Should the PIC membership be broadened to accommodate this wider role in the community?
- Will widening the partnership role of PIC over-extend the private sector volunteer members of the councils?
- Should PICs be encouraged to pursue a broader role in the community under current legislative authority or are amendments to JTPA and other authorizing statutes necessary?
- How can extension of the local public-private partnership be carried out most effectively, in concert with the locally-elected officials?

Roberts T. Jones,

Acting Assistant Secretary of Labor.

Date: July 29, 1988.

[FR Doc. 88-18230 Filed 8-11-88; 8:45 am]

BILLING CODE 4510-30-M

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 4 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wage determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefit determined in these dicisions shall, in accordance with the provision of the foregoing statutes, constitute the minimum wages payable of Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S-3504, Washington, DC 20210.

Modifications to General Wage Determination Decisions

The numbers of the decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by volume, State, and page number(s). Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I:

District of Columbia:
DC88-1 (Jan. 8, 1988) ..... pp. 78-81-82.
Florida:
FL88-1 (Jan. 8, 1988) ..... pp. 100-101.
New York:
NY88-2 (Jan. 8, 1988) ..... pp. 687, 697.
NY88-3 (Jan. 8, 1988) ..... pp. 702-708.
NY87-7 (Jan. 8, 1988) ..... p. 739.
NY87-13 (Jan. 8, 1988) ..... p. 803.

Volume II:

Ohio:
OH88-29 (Jan. 8, 1988) ..... pp. 824, 833, 856a.

Volume III:

Alaska:
AK88-1 (Jan. 8, 1988)..... p. 2.
Idaho:
ID88-1 (Jan. 8, 1988)..... pp. 142, 144, 147, pp. 149-150.
Oregon:
OR88-1 (Jan. 8, 1988)..... pp. 302-304, pp. 306-309.
Washington:
WA88-1 (Jan. 8, 1988)..... pp. 360-364
WA88-2 (Jan. 8, 1988)..... pp. 386-388
WA88-6 (Jan. 8, 1988)..... p. 412
WA88-7 (Jan. 8, 1988)..... p. 414

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and Related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country. Subscriptions may be purchased from; Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 783-3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the three separate volumes, arranged by State. Subscriptions include an annual edition (issued on or about January 1) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC, this 5th day of August 1988.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 88-18028 Filed 8-11-88; 8:45 am]

BILLING CODE 4510-27-M

Mine Safety and Health Administration

[Docket No. M-88-119-C]

Kannan Mining Co., Inc.; Petition for Modification of Application of Mandatory Safety Standard

Kannan Mining Company, Inc., HC 85, Box 2651, Whitesburg, Kentucky 41858 has filed a petition to modify the application of 30 CFR 75.1710 (cabs and canopies) to its Mine No. 1 (I.D. No. 15-15608) locate in Letcher County, Kentucky. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that cabs or canopies be installed on the mine's electric face equipment.

2. Petitioner states that the use of cabs or canopies would result in a diminution of safety to the miners affected because the cabs or canopies would limit the operator's visibility. The cabs or canopies could strike roof supports due to uneven roof and soft or uneven bottom. The cabs or canopies could also cut electrical cables, resulting in electrical shock.

Petitioner further states that if cabs or canopies are used, ventilation would be difficult to maintain. The limited visibility would result in the face curtains being torn down.

4. For these reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before (September 12, 1988). Copies of the petition are available for inspection at that address.

Dated: August 8, 1988.

Patricia W. Silvey,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 88-18323 Filed 8-11-88; 8:45 am]

BILLING CODE 4510-43-M

Occupational Safety and Health Administration

[V-88-2]

Bendix Friction Materials Division of the Automotive Sector of Allied-Signal Inc.; Application

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTIONS: (1) Notice of application for variance and interim order; and (2) Grant of interim order.

SUMMARY: This notice announces the application of the Bendix Friction Materials Division of the Automotive Sector of Allied-Signal Inc. for a temporary variance and an interim order pending a decision on the application for variance from the regulation prescribed in 29 CFR 1910.1001(o)(2)(viii) concerning start-up dates for methods of compliance with the Occupational Standard for Exposure to Asbestos. It also announces the granting of an interim order until a decision is rendered on the application for a variance.

DATES: The effective date of the interim order is September 12, 1988. The last date for interested persons to submit comments is September 12, 1988. The interim order shall remain in effect until October 20, 1988 or until a decision is rendered on the application for variance, whichever occurs first.

ADDRESS: Send comments or requests for a hearing to:

Office of Variance Determination, Occupational Safety and Health Administration, U.S. Department of Labor, Third Street and Constitution Avenue NW., Room N3653, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT:

James J. Concannon, Director, Office of Variance Determination, at the above address, Telephone: (202) 523-7193

or the following Regional and Area Offices:

U.S. Department of Labor, 201 Varick Street, Room 670, New York, New York 10014

U.S. Department of Labor, Leo W. O'Brien Federal Building, Clinton Avenue and North Pearl Street, Room 132, Albany, New York 12207

SUPPLEMENTARY INFORMATION:

Notice of Application

Notice is hereby given that the Bendix Friction Materials Division of the Automotive Sector of Allied-Signal Inc., facility located at Cohoes and Tibbits Avenue, Green Island (Troy), New York 12181 has made application pursuant to section 6(b)(6)(A) of the Occupational Safety and Health Act of 1970 (84 Stat. 1590; 29 U.S.C. 655) and 29 CFR 1905.10 for a temporary variance and an interim order pending a decision on the application for a variance from the standard prescribed in 29 CFR 1910.1001(o)(2)(viii) which specifies July 20, 1988 as the start-up date for 29 CFR 1910.1001(f)(1) which requires engineering controls and work practices to reduce and maintain employee exposure to asbestos to or below the exposure limit to the extent feasible.

The applicant is the Bendix Friction Materials Division of Allied-Signal Inc., with offices at 20650 Civic Center Drive, P.O. Box 5029, Southfield, Michigan

48086. The facility in New York for which this application is filed is engaged in the manufacture of brake linings, including friction materials containing asbestos.

The applicant certifies that employees who would be affected by the variance have been informed of the application by posting copies at all places where notices to employees are normally posted. Employees have also been informed of their right to petition the Assistant Secretary for a hearing. A copy of the application was given to the applicant's authorized employee representative.

Regarding the merits of the application, the applicant contends that it is unable to come into full compliance with the engineering control requirements of § 1910.1001(f)(1) by July 20, 1988 primarily because unanticipated geological conditions have been encountered by the contractor excavating for the underground foundation and storage area within the factory building for a sludge settling tank. The applicant has submitted an affidavit which states that the contractor has encountered rock formations that were not encountered in the test boring program, putting off the Applicant's compliance date to October 20, 1988.

The applicant contends that the engineering and work practice controls selected in its attempt to come into compliance with the requirements of § 1910.1001(f)(1) of the Asbestos Standard will cost an estimated $2,900,000.00. The modifications include conversion of the current dry operation to a wet process which is in an enclosed area and automated so as to reduce employee exposure to the manufacturing process. With the shift to the wet process, a settling tank becomes a necessary component.

The applicant states that the installation of the new system was scheduled to begin during the annual plant shutdown in July, with debugging complete by September. To comply with § 1910.1001(o)(2)(viii) effective date of July 20, 1988, the applicant has also planned an inventory buildup during the Spring of 1988 to carry it through the estimated mid-August completion date so that there would be no operation of the existing dry mix line during the period from July 20, 1988 through the anticipated start-up of the new line by September 1, 1988.

The applicant contends that the replacement of the existing dry-mix production lines with an automated single process wet mix production line is a major component of its compliance program. The replacement requires the excavation for and installation of a sludge tank to accommodate the new wet method of recovering dust from cutting and grinding operations. The dimensions of the tank are 44 feet by 15 feet and 12 feet deep. The actual excavation and foundation are, of course, even larger.

The applicant says that the contractor has further advised that the 14-week schedule cannot be shortened substantially in spite of the applicant's willingness to authorize overtime and scheduling of a second shift, because it is unable to obtain the necessary laborers. The labor shortage is attributable to recent increases in construction work in the region.

The applicant contends that, as a result of customer demand, it now appears that they must resume limited production operations with the existing dry mix line during this period to supply its customers in the auto industry or there is the risk of shutting down automobile production lines at Ford and Chrysler resulting in economic and personal dislocation. To permit continued production, the applicant is therefore requesting an interim order in addition to a temporary variance.

The applicant states that during the period for which the variance and interim order are being sought, it will continue to adhere to the existing comprehensive asbestos control program, which is described in its application as "Methods of Compliance Program," including the required housekeeping, respiratory protection program, medical surveillance, air sampling, employee training and continued designation of regulated areas.

The applicant states that it will make every effort to achieve compliance as quickly as possible, including the addition of a second shift or use of additional overtime in the event its contractor can overcome the labor shortage which have, in part, resulted in this request for variance.

Grant of Interim Order

It appears from the application for a temporary variance and interim an order that, as required by section 6(b)(6)(A) of the Act, the Bendix Friction Materials Division of the Automotive Sector of Allied-Signal Inc., Cohoes and Tibbits Avenue, Green Island (Troy), New York 12181 is unable to comply with the requirements of 29 CFR 1910.1001(o)(2)(viii) by the date required by the standard. It appears that the applicant is taking all available steps to safeguard its employees during the time needed to come into compliance with the standard. It further appears that an interim order is necessary to prevent undue hardship to the applicant and its employees pending a decision on the variance. Therefore, it is ordered, pursuant to the authority in section 6(b)(6)(A) of the Occupational Safety and Health Act of 1970, in 29 CFR 1905.10(c) and in Secretary of Labor's Order No. 9–83 (48 FR 35736), that the applicant shall continue to enforce the existing comprehensive asbestos control program as described in its application. All other provisions of the Asbestos Standard are unaffected by this order and therefore must be complied with in conjunction with the terms of this order.

As soon as possible, the applicant shall give notice of this interim order to affected employees by the same means required to be used to inform them of the application for a variance.

This interim order shall remain in effect until October 20, 1988, or until a decision is rendered on the application for variance, whichever is the earlier.

Signed at Washington, DC, this 8th day of August, 1988.

John A. Pendergrass,

Assistant Secretary of Labor.

[FR Doc. 88–18229 Filed 8–11–88; 8:45 am]

BILLING CODE 4510-26-M

Pension and Welfare Benefits Administration

Advisory Council on Employee Welfare and Pension Benefits Plans; Meeting

Pursuant to section 512 of the Employee Retirement Income Security Act of 1974 (ERISA) 29 U.S.C. 1142, a meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans will be held on Thursday, September 8, 1988, Room N–3437C, U.S. Department of Labor Building, Third and Constitution Avenue, NW., Washington, DC.

The purpose of the meeting, which will begin at 9:30 a.m., is to consider items listed below and to invite public comment on any aspect of the administration of ERISA.

1. General Business of the Advisory Council.

2. Status report of the Access to Health Work Group.

3. Status report of the Retiree Health Work Group.

4. Status report of the 415 Limit Committee.

5. Reporting and Disclosure Work Group to complete review of remaining items on Financial Reporting.

6. Open Discussion of Special issues:

(a) National Retirement Income Policy.

(b) Other.

7. Statements from the Public.

Members of the public are encouraged to file a written statement pertaining to any topic concerning ERISA by submitting 20 copies on or before September 6, 1988, to William E. Morrow, Deputy Executive Secretary, ERISA Advisory Council, U.S. Department of Labor, Room N-5677, 200 Constitution Avenue, NW., Washington, DC. 20210. Individuals wishing to address the Advisory Council should forward their request to the Deputy Executive Secretary or telephone (202/523-8753). Oral presentations will be limited to ten minutes, but an extended statement may be submitted for the record.

Organizations or individuals may also submit statements for the record without testifying. Twenty (20) copies of such statements should be sent to the Deputy Executive Secretary of the Advisory Council at the above address. Papers will be accepted and included in the record of the meeting if received on or before September 6, 1988.

Signed at Washington, DC, this 9th day of August, 1988.

David M. Walker,

Assistant secretary for Pension and Welfare Benefit Administration.

[FR Doc. 88-18320 Filed 8-11-88; 8:45 am]

BILLING CODE 4510-29-M

Advisory Council on Employee Welfare and Pension Benefits Plans; Work Group Meeting

Pursuant to the authority contained in section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, a public meeting of the Work Group on Access to Health Care of the Advisory Council on Employee Welfare and Pension Benefit Plans will be held at 10:00 a.m., Friday, September 9, 1988, in Room N-3437C, U.S. Department of Labor Building, Third and Constitution Avenue, NW., Washington, DC 20210.

This eight member work group was formed by the Advisory Council to study issues relating to access to health care. The purpose of the September 9 meeting is to obtain further testimony bearing on the potential impact and implications of proposed access to health care legislation—both at the federal and state level—with respect to the Department of Labor's role under ERISA. Of particular interest in this regard are the issues raised by legislative proposals based on an employment relationship as contrasted with non-employment based proposals. On July 13, 1988 the Work Group received testimony concerning the recently enacted Massachusetts access to health care legislation, Senator Kennedy's bill, S-1265, The Minimum Health Benefit For All Workers Act of 1987, alternative approaches endorsed by the Health Insurance Association of America, and areas of interest and concern being explored by the Small Business Administration and Department of Labor's Office of Research & Economic Analysis. At the July 13 meeting testimony was received mainly from public officials. The Work Group now wishes to provide an opportunity to employee representatives, employer representatives, service providers, the medical profession, and other interested individuals and groups with a vital interest in the subject matter, to present their views and or submissions for the Work Group's consideration.

Individuals, or representatives of organizations, wishing to address the work group should submit written requests on or before September 6, 1988 to William E. Morrow, Deputy Executive Secretary ERISA Advisory Council, U.S. Department of Labor, Room N-5677, 200 Constitution Avenue, NW., Washington, DC 20210. Oral presentations will be limited to ten minutes, but witnesses may submit an extended statement for the record.

Organizations or individuals may also submit statements for the record without testifying. Twenty (20) copies of such statements should be sent to the Deputy Executive Secretary of the Advisory Council at the above address. Papers will be accepted and included in the record of the meeting if received on or before September 6, 1988.

Signed at Washington, DC, this 9th day of August, 1988.

David M. Walker,

Assistant Secretary for Pension and Welfare, Benefits Administration.

[FR Doc. 88-18319 Filed 8-11-88; 8:45 am]

BILLING CODE 4510-29-M

NUCLEAR REGULATORY COMMISSION

Abnormal Occurrences for First Quarter CY 1988; Dissemination of Information

Section 208 of the Energy Reorganization Act of 1974, as amended requires the NRC to disseminate information on abnormal occurrences (i.e., unscheduled incidents or events which the Commission determines are significant from the standpoint of public health and safety). The following incidents at NRC licensees were determined to be abnormal occurrences (AOs) using the criteria published in the **Federal Register** on February 24, 1977 (42 FR 10950). The abnormal occurrences are described below, together with the remedial actions taken. The events are also being included in NUREG-0090, vol. 11, No. 1 ("Report to Congress on Abnormal Occurrences: January-March 1988"). This report will be available in the NRC's Public Document Room, 1717 H Street, NW., Washington, DC about three weeks after the publication date of this **Federal Register** Notice.

Nuclear Power Plants

88-1 Potential for Common Mode Failure of Safety-Related Components Due to a Degraded Instrument Air System at Fort Calhoun

One of the general AP criteria notes that major deficiencies in design, construction, use of, or management controls for licensed facilities or material can be considered an abnormal occurrence. In addition, one of the AO examples notes that a major deficiency in design, construction, or operation having safety implications requiring immediate remedial action can be considered an abormal occurrence.

Date and Place—September 23, 1987; Fort Calhoun, a Combustion Engineering-designed pressurized water reactor, operated by Omaha Public Power District, and located in Washington County, Nebraska.

Nature and Probable Consequences—While the licensee was performing a surveillance test of emergency diesel generator (EDG) 2, the EDG tripped off due to high temperatures in the engine cooling water system. Investigation revealed an instrument air problem (water in the system) which could have resulted in a potential for common mode failure of redundant EDG 1 and other safety-related components at the plant.

Many U.S. light water reactors rely upon air systems to activate or control many safety-related, as well as many non-safety related, components. The instrument air system activates pneumatic controls, valves, dampers, and similar devices on the components. Through the years, there have been numerous problems caused by either failures in the air system components, or failures in air-controlled components which have been degraded by contaminated air. Many problems have been caused by air system design, operation, or maintenance deficiencies. The circumstances associated with the Fort Calhoun event are as follows.

During May 1985, the licensee modified its fire-protection sprinkler system in the diesel generator rooms, where extremely cold weather had caused water to freeze and crack the pipes. Rather than keep this piping filled with water all the way to the sprinkler head, the licensee devised a "dry pipe" arrangement by which pressurized air would fill the pipe for several feet upstream from the sprinkler head, keeping water in check that would be released in the event of a fire. To accomplish this, the instrument air system was connected to the sprinkler system, and check valves were installed to keep water from flowing back into the air pipes. However, the licensee failed to establish a test program that would assure that the check valves would perform satisfactorily in service.

On July 6, 1987, these check valves failed to work, and water entered the air system after the licensee had tested its "dry pipe" sprinkler. After this incident, the licensee cleaned and inspected the check valves to see that they operated, then reconnected the two systems. However, the licensee failed to assure that the cause was properly determined and that appropriate corrective actions had been taken. For example, no dew point measurements were taken to verify that the air system complied with the design bases for the dewpoint maximum limit; and no review was performed to determine whether or not other instrument air/pressurized water interfaces existed. In addition, even though a formal program was established to perform blowdowns of the air system, the air accumulators for the EDG air motors were not included in either the piping drawings or procedures; therefore the accumulators were not checked for the presence of water.

On August 25, 1987, the licensee again found water in the instrument air system, discovering this time that the situation resulted from an interconnection with an air-actuated valve in the plant's potable water system.

On September 23, 1987, after EDG 2 tripped on high temperature during a surveillance test, the licensee determined that the most likely cause of the event was the failure of the exhaust damper on the diesel radiator to open. Without the damper open, no radiator cooling air flow was available and the engine cooling water temperatures increased.

The licensee disassembled the air motor used for opening and closing the radiator exhaust damper and found an accumulation of water in the motor air accumulator, apparently from the July 6, 1987 water intrusion event. The licensee found that the pilot valve used to direct air into the motor was coated with a gummy substance. The radiator exhaust damper air motor uses the plant instrument air system as a prime mover. The licensee cleaned up and reassembled the air motor on EDG 2. Subsequent testing on the EDG 2 damper indicated the damper operated satisfactorily.

Subsequently, the air motor on EDG 1 was disassembled and the same problem was found as in EDG 2. It was also cleaned up, reassembled, and tested satisfactorily.

Cause or Causes—The root cause of this incident was due to a breakdown in the ability of management to control activities that affect quality at the Fort Calhoun Station. A plant system had been modified without adequate evaluation of the safety implications and improper testing following the modifications. This breakdown resulted in the plant being operated in an unanalyzed condition where a potential for common mode failure condition existed.

Actions Taken To Prevent Recurrence

Licensee—An extensive corrective action program has been undertaken to ensure that all water is removed from the air system and to ensure that all safety-related components function normally. The interface between the instrument air system and the diesel generator fire protective system has been removed. A walk down of the entire plant instrument air system was made to assure that any other interconnections to the fire protection system were either isolated or removed.

More frequent inservice testing inspections (ISI) will be performed on various components operated by the instrument air system until there is assurance that they have not been adversely affected. For components that cannot be tested during plant operation, justification is to be provided to continue operation until the next scheduled or forced cold shutdown in excess of 48 hours.

NRC—An initial inspection was performed by NRC Region IV during the period of September 23 through October 2, 1987. The inspection findings were formally sent to the licensee on October 23, 1987. On October 29, 1987, an enforcement conference was held with the licensee at the NRC Region IV office to discuss the issues related to the event.

A special review team from NRC Region IV performed a follow-up inspection during the period of November 2–6, 1987. The inspection findings were formally sent to the licensee on December 10, 1987.

During the inspection, several violations of NRC requirements were found. Consequently, on February 22, 1988, the NRC issued to the licensee a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $175,000.

The licensee was cited for modifying a plant system without adequately evaluating the safety implications, including the possibility that water in air lines could simultaneously disable several safety systems. The licensee was further cited for failing to (1) test the check valves designed to prevent water from backflowing into the air lines; (2) provide appropriate instructions or procedures to personnel involved with the modified systems; (3) recognize the inoperability of the disabled diesel generator or test the second diesel for operability; (4) declare an "unusual event" when the diesel generator was inoperable; (5) notify the NRC promptly of these conditions; and (6) correct the degraded safety conditions promptly and adequately.

Instrument air system problems are being addressed generically by NRC in several ways. A staff task group is continuing to examine the need for further improvements in instrument air systems under Generic Issue 43, "Reliability of Air Systems." Operating experience is being updated and fed back to the industry, such as the updated case study NUREG-1275, Vol. 2, "Operating Experience Feedback Report—Air System Problems," published in December 1987, and NRC Information Notice No. 87-28, Supplement 1, "Air System Problems at U.S. Light Water Reactors." NRC activities focused on improving air systems are continuing.

The licensee has paid the civil penalty. The NRC will assure that the corrective actions proposed are complete and satisfactorily implemented.

88-2 Common Mode Failures of Main Steam Isolation Valves at Perry Unit 1

One of the general AO criteria notes that major degradation of essential safety-related equipment can be considered an abnormal occurrence. In addition, one of the AO examples notes that major degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary can be considered an abnormal occurrence. Also, another AP example notes that recurring incidents which create major safety concern can be considered an abnormal occurrence.

Date and Place—October 29 and November 3, 1987; Perry Unit 1, a General Electric-designed boiling water reactor, operated by Cleveland Electric Illuminating Company, and located in Lake County, Ohio.

Nature and Probable Consequences—On both of the above dates, Unit 1 experienced a common mode failure during testing of the "D" steam line main steam isolation valves (MIVs). Both the inboard and outboard "D" MSIVs filed to close within the required time limit.

The MSIVs are part of the primary system and are provided to limit the release of radioactive materials to the environment or to limit reactor vessel inventory loss during a design basis accident. Therefore, the failures of both the inboard and outboard "D" MSIVs to fast close were major degradation of the primary containment boundary and costitute a major degradation of safety-related equipment. The severity of a radioactivity release outside containment depends on the total that radioactive steam escapes to the environment and the activity level in the reactor collant system during that event. The circumstances associated with the events are as follows.

The Perry Unit 1 has four main steam lines which carry steam from the reactor to the plant's turbine-generator. Eadh line hs two automatically operated MSIV valves—oneinside the reactor containment (inboard MSIV) and one outside (outboard MSIV)—which are designed to close quickly in the vent of a steam line rupture. One valve closing would be sufficient to stop the flow of steam, which contains radioactivity and which could be released to the environment through a ruptured pipe, if the other valve did not close.

The valves are periodcially tested to assure that they meet the required test closure time of five seconds in what is called the "fast closure test." The valves are operated by pneumatic pressure and by compressed springs. Closure of the MSIVs is controlled by Automatic Switch Company (ASCO) dual solenoid valves.

On October 29, 1987, as part of the startup test program the licensee test each MSIV valves (two on each steam line). The twovalves on the "D" steam line an done on a second line failed to close in the five second test period. Subsequent testing, however, showed the vlaves to meet the test criteria, and the unit remained in operation.

On Novebmer 3, 1987, the valves were retested at the request of NRC Region III, prior to the licensee performing a full reacator isolation test (which involves simultaneous closure of all MSIVs) in its startup test program. The two "D" MSIVs again failed to close within the time limit—one closed in 18 seconds and the second did not close until the valve switch was cycled again in the control room after about 160 seconds. The licensee commenced an orderly shutdown of the reactor to develop a disassembly and troubleshooting program.

The licensee found that the elastomer discs and O-rings in the ASCO solenoid valves which controlled the failed MSIVs showed significant deterioration and degradation. It was concluded that the most probable cause was prolonged exposure of the ASCO solenoid valves to a high temperature environment, resulting from steam leaks in the vicinity of the valves. These valves were not intended nor designed for use in such conditions. The licensee replaced or rebuilt all of the ASCO solenoid valves associated with operation of the MSIVs. The plant resumed operation November 13, 1987, and successfully completed the full reactor isolation startup test.

On November 29, 1987, the licensee was performing a different test on the MSIVs—a fast closure operability check—when it was determined that the inboard valve on the "B" steam line would not close and stay closed as it should during the test. Again, the licensee commenced an orderly shutdown of the reactor to determine the cause of failure.

Disassembly and inspection of the failed ASCO valve revealed the presence of a sliver, and two smaller particles, of foreign material in the solenoid housing assembly. The foreign material was deteriorated body gasket materials that had remained inside the valve when it was rebuilt in early November. The licensee concluded that the sliver of material caused mechanical binding of the solenoid valve.

The licensee replaced all of the dual solenoid valves (including the ones previously replaced earlier in November). The plant was restarted on December 8, 1987.

The licensee performed an analysis of the radioactivity expected to be released to the environment if a steam line was not isolated for 18 seconds and a steam line break occurred outside containment. Their analysis assumed that other mitigating systems (ECCS) performed as designed. The maximum primary coolant activity permitted by technical specification operating limits was assumed plus any additional activity which may be released as a result of reactor scram and vessel depressurization, but no additional fuel failures as a result of the postulated accident. Calculation results using the mass release used in the FSAR and data used for a GE computer code were about 192 rem and 80 rem, respectively, for thyroid dose at the exclusion boundary. Their calculation predicted that Part 100 limits (300 rem) would have been exceeded if the line remained unisolated for 79 seconds or greater.

NRC staff, using conservative design basis loss of coolant accident source terms, determined that 10 CFR Part 100 limits would be exceeded for such an event with two redundant MSIVs failing to fast close within 18 seconds. This is the limiting case and would exceed the releases for other design basis events such as a steam line break outside containment.

In this case, the root cause of the events (deterioration due to high temperature) may have, over time, caused further deterioration of the valves that failed, as well as deterioration of additional valves. Therefore, there was serious concern regarding the reliability of the MSIVs to perform their safety function to mitigate the consequences of design basis accidents.

The NRC sent fact-finding Augmented Inspection Teams (AITs) to the site after both the November 3 and November 29, 1987 events to determine the cause(s), conditions, and circumstances of the MSIV failures.

Cause or Causes—For the October 29 and November 3, 1987 events, the AIT determined that the most probable cause of the testing failures was a malfunction of the ASCO solenoid valves that operate the MSIVs due to deteriorating parts inside the solenoid valves. The deterioration occurred as a result of high temperatures caused by steam leaks in the vicinity of the valves. The deteriorated parts impeded the operation of the solenoid valves.

For the November 29, 1987 event, the AIT concluded that deteriorated materials had remained inside the solenoid valve when it was rebuilt in early November. These materials impeded the valve operation.

Actions Taken To Prevent Recurrence

Licensee—The licensee increased its testing frequency for MSIVs with the new solenoid valve actuators and modified its maintenance procedures to require replacement or complete rebuilding rather than repair of any malfunctioning solenoid valves.

The licensee repaired the steam leaks and installed temperature monitors to detect any future steam leaks which could degrade the ASCO solenoid valves.

NRC—As previously mentioned, NRC AITs were sent twice to Perry Unit 1.

While primarily fact finding missions, the AITs also identified a number of issues (which were given to the licensee for its consideration) which may be examined for possible enforcement in subsequent inspections. The AIT report (Inspection Report No. 50-440/87-24) covering the October 29 and November 3, 1987 events was sent to the licensee on January 22, 1988. The AIT report (Inspection Report No. 50-440/87-27) covering the November 29, 1987 event was sent to the licensee on February 10, 1988. NRC issued Information Notice No. 88-43, "Solenoid Valve Problems," on June 23, 1988, addressing the technical details and concerns identified by this event and several others.

88-3 Craked Pipe Weld in Safety Injection System at Farley Unit 2

One of the AO examples notes that a major degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary can be considered an abnormal occurrence. The specific reportability consideration of this pipe weld failure is due to the possible generic implications from a thermal cycle mechanism not previously experienced in the industry.

In addition, the event raised possible generic implications; another AO example notes that incidents with implications for similar facilities (generic incidents), which create major safety concern, can be considered an abnormal occurrence.

Date and Place—December 9, 1987; Farley Unit 2, a Westinghouse-designed, 3-loop pressurized water reactor, operated by the Alabama Power Company (the licensee) and located in Houston County, Alabama.

Nature and Probable Consequences—An unisolable leak was discovered in a safety injection system (SIS) pipe while Unit 2 was being restarted after a refueling outage. The significance of this event is that a generic safety question may exist in that more than one unisolable emergency core cooling system (ECCS) pipe failure may occur. Subjecting the flawed piping to excessive stresses induced by a seismic event, water hammer or other cause, conceivably could result in simultaneous double-ended failure of more than one ECCS pipe. The circumstances associated with the event are as follows.

The licensee had noted increased moisture and radioactivity (1000 to 2000 counts per second) within containment. The unidentified leak rate for the reactor coolant system (RCS) was determined to be 0.7 gpm. The technical specifications permit leakage up to 1.0 gpm. After entering containment to identify the location of the leak, licensee personnel determined that the leak could not be isolated. The reactor was taken to cold shutdown to facilitate repair.

After failing to detect crack indications by liquid penetrant testing (PT) methods, the licensee located an indication of a through-wall crack using ultrasonic testing (UT) in the 6-inch ECCS piping connected to the cold leg of RCS loop B. The indication was located at a weld connecting an elbow and a horizontal pipe section between the isolation check valve (VO51B) and the reactor coolant piping. The indication was on the bottom of the pipe and extended circumferentially 60 degrees in both directions from the bottom inside of the pipe. The crack, which was confirmed by radiography, extended through the wall for approximately one inch at the center of the indication and extended about six inches on the inside piping surface.

The licensee initiated a progressive UT examination plan for those welds adjacent to the cracked weld and for all similar system welds on all three loops in both Unit 1 and Unit 2. The examination included three welds in Unit 2 loop B cold leg of the SIS, upstream of valve VO51B. The examination did not reveal any relevant UT indications.

A complete system walkdown of all three SIS loops in both Units 1 and 2, performed to determine if any pipe restrictions, leakage, or other problems were evident, identified no additional significant problems.

The faulted piping assembly (containing the vertical pipe, the elbow and the horizontal pipe) was shipped to the Westinghouse Research and Development Laboratory in Pittsburgh, Pennsylvania for evaluation. The metallurgical examinations were performed on a three inch wide ring section containing the weld joint exhibiting the circumferential cracking. The evaluations included surface examinations, metallographic examinations, fractographic examinations and chemistry evaluations.

Based on the results of these evaluations, it was concluded that the observed cracking in the SIS pipe to elbow joint was caused by a high cycle fatigue mechanism. Stress concentration at the knee of the standard counterbore region and normal surface machining grooves contributed to the crack initiation. Neither weld defects nor corrosion attack contributed in any significant way to the joint failure.

The visual and metallographic examinations showed that the weld had failed as a result of fatigue after roughly one million stress cycles. The licensee examined the operating records and determined that the number of stress cycles imposed, by starting up and shutting down the plant and by SIS initiation, was significantly less than the relevant design criteria.

On the basis of this information, the licensee postulated that the weld stress loads were either (1) thermal and created by valve leakage or convective flow cells or (2) mechanical and created by flow-induced vibrations. To test these postulations, the licensee replaced the failed piping and installed sensors for temperature and acceleration near the location of the failed weld and on the other side of the check valve at a location about two feet upstream of the failed weld. The licensee also installed sensors at similar locations on the ECCS pipe connected to RCS loop C.

Following repair, the reactor was restarted and taken to steady state full power operation. Data obtained demonstrated that there was an adverse temperature distribution in the loop B ECCS piping. The maximum circumferential temperature difference at the location of the failed weld was about 215°F. Further the temperature at the bottom of the pipe fluctuated as much as 30°F in 30 seconds. This difference in temperature distribution was caused by failure of a valve in the bypass pipe around the boron injection tank to seat properly. This leading valve is believed to have set up a thermal cycling leading to failure of the weld. Leakage through the valve apparently caused the check valves in the loop B ECCS pipe to partially open, or chatter, admitting relatively cold coolant to the unisolable portion of the pipe between the nozzle and the first check valve. Thus, cold water on the bottom of the pipe created thermal stress which was cyclic in nature causing excessive stresses and a resultant pipe crack.

Data from the temperature sensors for loop C ECCS piping indicated that the check valves in that pipe were not chattering and that the temperature distribution was normal. Further, none of the accelerometers indicated adverse mechanical stress cycling.

The event may have generic safety implications for other plants which have dual purpose pumps used for charging the RCS with coolant during normal operation and for injecting emergency core coolant at high pressure following an accident. During normal operation, with one of the pumps providing charging flow to the RCS via the normal charging piping and with a leaky valve allowing coolant to flow to the ECCS manifold, pressure in the manifold will exceed RCS pressure. This would allow

check valves in the ECCS piping to open admitting relatively cold coolant to the RCS. The flow rate via this additional path or paths would be determined by the amount of leakage through the leaking valve. If the check valves in more than one ECCS pipe open, then more than one unisolable ECCS system leak may occur. Subjecting the weakened piping to excessive stresses induced by a seismic event, water hammer, or some other cause conceivably could result in simultaneous double-ended failure of more than one ECCS pipe.

Cause or Causes—As discussed in more detail above, the cause of the pipe cracking was attributed to valve leakage which resulted in thermal cycling of the pipe.

Actions Taken to Prevent Recurrence

Licensee—The initial actions were to replace the piping associated with the failed weld. The 90° elbow and straight runs of pipe at each end of the cracked elbow to pipe weld were removed from the SIS cold leg on loop B.

The initial corrective actions taken to prevent recurrence were to provide a means to assure that the pressure upstream of the check valve does not exceed RCS pressure, thereby reducing the possibility of its partially opening or chattering. Possible changes for long-term corrective actions are under review.

NRC—The licensee examinations and initial corrective actions were reviewed by NRC Region II personnel during an inspection on Decmeber 12–16, 1987. The inspection identified no violations of NRC requirements. The inspection report was forwarded to the licensee on January 29, 1988. On January 15, 1988, the licensee met with the NRC staff to review their corrective actions and to better define the generic aspects of the issue. As a side issue, the licensee's ECCS analysis required licensee and Westinghouse reevaluation of a postulated double-ended SIS pipe break. The licensee's corrective actions and the ECCS reanalysis remain under review by the NRC staff.

On January 27, 1988, the NRC issued Information Notice No. 88–01, "Safety Injection Pipe Failure," to all holders of operating licenses or construction permits for nuclear power reactors to inform them not only of the Farley event, but also of the potential generic problem concerning the reliability of piping in safety-related systems due to valve leakage which may result in thermal cycling of the piping. On June 22, 1988, the NRC issued Bulletin No. 88–08, "Thermal Streses in Piping Connected to Reactor Coolant Systems," to request that licensees (1) review their reactor coolant systems (RCSs) to identify any connected, unisolable piping that could be subjected to temperature distributions which would result in unacceptable thermal stresses and (2) take action, where such piping is identified, to ensure that the piping will not be subjected to unacceptable. thermal stresses.

Other NRC Licensees

(Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

88–4 Diagnostic Medical Misadministration

The general AO criterion notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—November 23, 1987; Veteran's Administration Medical Center, Albuquerque, New Mexico.

Nature and Probable Consequences—A patient was administered 50 millicuries of technetium-99m (as sodium pertechnetate) instead of 3 millicuries of thallium-201 prescribed by the physician.

The purpose of the administration was for a Myocardial Perfusion Stress Test. The licensee reported that there were no deleterious effects to the patient. The licensee calculated that the patient incurred the following doses: thyroid—6.1 to 10.2 rads; stomach—5.1 to 15.3 rads; colon—5.1 to 15.3 rads; gonads—0.5 to 2.0 rads; and whole body—0.5 rad.

Cause or Causes—The misadministration was caused by a student technolgist selecting the wrong syringe from the dosage cart.

Actions Taken To Prevent Recurrence

Licensee—The student technologist was reprimanded, new procedures for radiopharmaceutical labeling and handling will be implemented, personnel will be retrained, and the supervision of personnel will be improved.

NRC—NRC Region IV telephoned the radiation safety officer reporting this misadministration for additional details on the incident. Those details were subsequently provided by a February 1, 1988 memorandum from the licensee. The incident will be reviewed during a special NRC inspection at the center.

88–5 Breakdown in Management Controls at Georgia Institute of Technology Research Reactor Facility

One of the general AO criteria notes that major deficiencies in design, construction, use of, or management controls for licensed facilities or material can be considered an abnormal occurrence.

Date and Place—This occurrence addresses licensee performance over a period of time until January 20, 1988, when the NRC Issued an Order Modifying License (effective immediately) to the Georgia Institute of Technology (Georgia Tech) regarding their research reactor (GTRR). The GTRR is a 5 megawatt (thermal) facility, located in Atlanta, Georgia, and utilized for teaching and research including the performance of irradiation experiments.

Nature and Probable Consequences—The NRC Order required the licensee to cease utilization of the reactor facility for irradiation experiments until certain conditions are met and the NRC approves the resumption of irradiation experiments.

NRC concerns with regard to the licensee's management control has been the subject of enforcement actions in the past. An inspection conducted February 9–23, 1987, which included a review of the licensee's operations program, identified numerous failures to comply with NRC regulatory requirements. The areas of non-compliance included inadequate procedures, failures to follow procedures, and problems in keeping adequate records documenting compliance with NRC requirements. Based on these inspection findings, the NRC raised concerns about programmatic weaknesses in the licensee's implementation of Technical Specification requirements.

Inspections conducted February 17–23 and April 7–10, 1987, which included a review of the licensee's operations and radiation protection programs, also identified significant failures to comply with NRC regulatory requirements in the same areas described above. The findings of these inspections clearly indicated the licensee's need for improved management control to ensure adherence to NRC requirements and safe performance of licensed activities. On May 4, 1987, an enforcement conference was held at the NRC Region II office in which the licensee outlined steps to be implemented to improve management controls over operations and health physics at the facility to assure safe operation. These actions included a change in the research facility's organizational structure.

The events leading to issuance of the NRC Order were identified during recent inspections which showed that the licensee's actions have not been fully successful and indicated that management control problems continue. On December 16, 1987, while reviewing management reorganization concerns

for the GTRR program, an NRC inspector learned of a contamination event which occurred at the reactor facility during the week of August 17, 1987. The event involved the improper opening of an irradiated material container which resulted in the release of radioactive contamination within the reactor containment building. At the time of the December 1987 NRC inspection, a detailed description and evaluation of the event had not been prepared by licensee staff or management. This inspection was continued on January 4–5, 1988, and a team inspection was conducted from January 14–22, 1988.

The inspection findings revealed that the experiment conditions and manipulation of the experiment materials resulted in unexpected elevated radiation levels from the experiment container and also the unmonitored release of cadmium-115 in the reactor building. The dose rate at one foot from the experiment material was approximately 3 rem per hour on August 18, 1987, and qualitative measurements of radioactive contamination indicated levels on masolin wipes of approximately 20 millirem per hour on August 19, 1987.

The following violations were identified from the inspection findings: failure to have adequate procedures and failure to follow procedures for handling and manipulating experiment material and for surveying and evaluating potential radiological hazards; failure to conduct adequate radiation surveys of the reactor building and GTRR personnel and their personal property for evaluation of exposure to radioactive material; failure to conduct adequate air sampling and bioassay analyses for evaluation of personnel exposure to airborne radio-active material during experiment and decontamination activities; and failure to document and maintain records of radioactive material contamination surveys conducted.

At the time of the inspection the licensee had failed to complete a thorough review of the August 1987 contamination event regarding its cause or causes, nor had any corrective measures been implemented as of January 5, 1988 to prevent recurrence during future experiments.

The issuance of the NRC Order was a direct result of NRC concerns over the licensee's past performance, their unsatisfactory slow rate of improvement, and, most importantly, the licensee's lack of management control needed to assure that continued irradiation experiments would not result in more significant safety problems.

Cause or Causes—The root cause was a lack of regard for and adherence to procedures, and a lack of management control over licensed activities.

Actions Taken To Prevent Recurrence

Licensee—The licensee voluntarily shut down the GTRR on February 15, 1988. The enforcement history and recent inspection findings were discussed with the licensee at an enforcement conference held at the NRC Region II office on February 23, 1988. The licensee addressed the violations identified and presented an action plan directed towards upgrading their operations and health physics programs. Also, the licensee committed not to restart the reactor without NRC concurrence.

NRC—The January 20, 1988 NRC Order required the licensee to immediately suspend certain activities under its NRC license until requirements of the Order are satisfied which includes: an assessment of management controls; review whether any other events similar to the August 1987 incident have occurred; assessment of personnel exposures for the August 1987 event, and any other similar events, and associated cleanup activities; review of health physics and operating procedures; identification of corrective actions and schedule for implementation; and development and implementation of necessary training programs.

On March 17, 1988, the NRC issued to the licensee a Confirmatory Order Modifying License (effective immediately) confirming the licensee's commitments made at the February 23, 1988 enforcement conference. The Order did not modify the conditions of the January 20, 1988 Order.

The inspection report forwarded to the licensee on February 10, 1988, identified several apparent violations of NRC requirements. However, no formal Notice of Violation was issued at the time since the apparent violations are under consideration for escalated enforcement action.

88–6 Release of Polonium-210 From Static Elimination Devices Manufactured by 3M Company

One of the AO examples notes that a series of events (where individual events are not of major importance), incidents with implications for similar facilities (generic implications), which create a major safety concern, can be considered an abnormal occurrence. In addition, one of the general AO criteria notes that a moderate release of radioactive material licensed by or otherwise regulated by the Commission can be considered an abnormal occurrence.

Date and Place—January 21, 1988; Ashland Chemical Company (Ashland) plant in Easton, Pennsylvania, and various other locations.

Nature and Probable Consequences—On January 22, 1988, the radiation safety consultant for Ashland reported to NRC Region I that radioactive contamination had been discovered at their plant on the previous day. Subsequent determination of the cause of the contamination led to extensive investigations which showed that similar contamination problems existed at many plants in many states.

The cause of the contamination involved the failure of static elimination devices manufactured by the Minnesota Mining and Manufacturing Company (3M Company), St. Paul, Minnesota, containing polonium-210 (Po-210). Po-210 decays by emission of a 5.3 MeV alpha particle and has a half life of 138 days. The devices in 3M Company's Model 900 series are used to ionize a stream of air in order to remove static electricity. Even-numbered models in the 900 series (Models 902, 902F, 906, and 908) are used in conjunction with compressed air; odd-numbered models (Models 905, 907, and 909) are used with blown air. (The devices used by Ashland were of the even-numbered models and were connected to a source of compressed air.) The 3M Company also manufactures bar-type static elimination devices.

The Po-210 in these devices is contained in microspheres of zirconium pyrophosphate that have been plated with nickel and are held in place with an epoxy adhesive. The microspheres are about 0.001 inch in diameter and are hard, dense, and insoluble. The 3M Company manufactures the devices under NRC License No. 22–00057–06 and distributes them to general licensees (such as Ashland) under NRC License No. 22–00057–32G as permitted by the general license provisions of 10 CFR § 31.5. Because general licensees lack the expertise to leak-test the devices, the 3M Company requires that the devices be leased for a one-year period, returned to the 3M Company, and tested for leakage of radioactivity.

The discovery at Ashland resulted from an investigation occasioned by a complaint from one of Ashland's customers that its product was radioactively contaminated. Subsequent to discovery of contamination at its Easton plant, Ashland conducted surveys at its other plants. On January 23, 1988, its plants at Dallas, Texas, was also found to be contaminated; its other

plants were free of contamination. Surveys were begun at other plants using the 3M devices, and contamination was discovered at a KTI Chemical Corporation plant in Carrollton, Texas, on January 28, 1988. On February 1, 1988, two beverage plants in Dallas, Texas, were found to be contaminated. At this time, the U.S. Food and Drug Administration (FDA) began investigation for possible product contamination at plants using the 3M Models 902, 902F, 906, and 908 devices where device failure had been found in the preceding years. No contaminated product has been found.

Inspectors from the NRC examined 3M Company records of quality assurance on returned devices for the years 1986 and 1987 and discovered a large number of devices that were leaking upon return to the 3M Company. Most of these failures had not been reported to the NRC because the 3M Company believed that the failure was caused by some kind of damage to the device. Inspectors from the NRC and individual states have now (as of late April 1988) surveyed scores of plants using 3M Company static elimination devices and have identified a large number of plants that show contamination levels exceeding 0.005 microcuries. It is expected that the total number of such plants may be several hundred. For each plant in which contamination was found, the contamination was not widespread; rather, it appears to result from discrete Po-210 particles.

Po-210 emits alpha radiation which will not penetrate the outer layers of the skin. The size and density of the Po-210 microspheres indicates that they are not respirable and, if ingested, they are expected to pass through the digestive tract in a short time without significant release to the bloodstream because they are very insoluble. Bioassay of workers at Ashland's plants at Easton, Pennsylvania and Dallas, Texas, demonstrated no uptake of polonium. No adverse health effects are expected because of the defective static elimination devices, and none have been found.

Cause or Causes—No cause for failure of the static elimination devices has been ascertained. A postulated cause is moisture or solvents in the environment that affect the epoxy adhesive, which holds the radioactive material in the device.

Actions Taken To Prevent Recurrence

Licensee (3M Company)—The licensee's investigation of the cause of the failures and possible corrective actions continues. The licensee is carrying out the requirements of the below described NRC Orders.

General Licensees—Plants where contamination has been found have been, or are being, cleaned up and returned to production. All 3M Company devices are being returned to the manufacturer (except as permitted by the February 18, 1988 NRC Order described below). As of mid-April 1988, about half of all static elimination devices have been returned to the 3M Company (this includes 86% of the devices used in food, beverage, pharmaceutical, and cosmetic applications). Of the devices returned, 1.84% had leakages greater than 0.005 microcuries.

NRC—On January 25, 1988, the NRC ordered the 3M Company to suspend distribution of Models 902, 902F, 906, and 908 devices; to inform users of these devices of the problem discovered by Ashland; to survey a suitable sample of users to ascertain the extent of the problem; and to determine the cause of the failure of the devices. On February 5, 1988, the NRC issued a confirmatory order, confirming the 3M Company's commitments to remove all devices with the above model numbers from applications related to the packaging of food, beverages, cosmetics, and pharmaceuticals. On February 12, 1988, the NRC ordered the 3M Company to remove all static elimination devices (not just the 900 series) from all applications relating to the production and packaging of food, beverages, cosmetics, and pharmaceuticals. These actions were coordinated with the FDA.

On February 18, 1988, the NRC ordered the 3M Company to suspend transfer of all static elimination devices using Po-210; to instruct users of the devices to return them to the 3M Company; to test returned devices for leakage and report any leakage to the NRC (or Agreement State) and the user; and to report the status of these activities to the NRC every 30 days. The February 18, 1988 NRC letter also ordered all general licensees using the 3M Company static elimination devices to suspend use of the devices and to return them to the 3M Company as soon as feasible but no more than 90 days from the date of the Order. An exception was made for continued use of the devices, under certain conditions, for applications where use of the device is essential for work place safety (e.g., where static electricity may pose a significant fire, explosion or other hazard). On April 13, 1988, the NRC Order of February 18, 1988 was modified to allow the 3M Company to respond to the show cause order by July 18, 1988.

The NRC actions were coordinated with the Agreement States. As of March 25, 1988 (the latest date, as of April 30, 1988, for which an estimate of total Agreement State efforts are available) the Agreement States had applied 8,224 professional staff-hours (equivalent to about 4.5 full-time staff persons) to conduct on-site surveys of facilities identified as possessing these sources. The Agreement States took appropriate enforcement actions when contamination was found and their survey data were incorporated into the NRC data base which served as a basis for NRC enforcement decisions.

Many of the non-Agreement States assisted NRC by surveying NRC generally licensed users of these devices at NRC's request and their survey data were also used by NRC in assessing the scope of the problem.

The International Atomic Energy Agency (IAEA) and regulatory and safety authorities in 44 countries were advised through the Department of State's cable system and directly via airmail of NRC concerns and subsequent actions related to the 3M static elimination devices. The IAEA and the safety contacts in all 44 countries received copies of NRC orders and background material on the defective devices in two separate mailings, dated February 12 and 19, 1988. Subsequent mailings also were sent to update the IAEA and foreign safety contacts on developments in this area. On March 31, 1988, to prevent further exports of the defective devices, NRC issued an order confirming that 3M would not be permitted to export any polonium-210 static elimination devices under the general license for export in 10 CFR Part 110.

88-7 Therapeutic Medical Misadministration

The general AO criterion notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—February 4, 1988; Medical X-Ray Center, Sioux Falls, South Dakota.

Nature and Probable Cosnequences—A patient was administered 7.5 millicuries of phosphorus-32 (as sodium phosphate) instead of 4.0 millicuries of the same radiopharmaceutical prescribed by the physician.

The purpose of administration was to treat polycythemia vera (excess blood red platelets). As a result of the misadministration, the patient received a dose of about 270 rads and 75 rads (to the bone marrow and whole body,

respectively) instead of about 145 rads and 40 rads, respectively, had the prescribed amount of pharmaceutical been administered. There were no apparent effects to the patient. The licensee reported that blood counts will be followed for several weeks post-therapy and that the last report on February 16, 1988, showed normal blood elements.

Cause or Causes—The misadministration was caused by a miscalculation of the dose by the technician.

Actions Taken To Prevent Recurrence

Licensee—The technician administering the dose was reinstructed in the proper technique for calculating therapy doses and for reviewing the written physician orders prior to administering the doses.

NRC—NRC Region IV telephoned the radiation safety officer reporting this misadministration for additional information and assurance that corrective action had been taken. The incident will be reviewed during the next NRC inspection at the medical center.

88-8 Therapeutic Medical Misadministration

The general AO criterion notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—Discovered on February 15, 1988; St. Joseph's Hospital, Milwaukee, Wisconsin.

Nature and Probable Consequences—On February 23, 1988, NRC Region III was notified by the licensee that an 86-year-old patient with a 10-year history of bladder cancer received a cobalt-60 therapeutic radiation dose of 2000 rads to the wrong side of his pelvis.

On January 19, 1988, the patient was admitted to the hospital with a severe right rib pain. A CAT scan of his abdomen (January 20), a bone scan (January 25) and mid-spine and pelvic scan (January 28) confirmed the patient had a metastatic cancer. The Radiation Oncologist determined that two local areas should be treated, the spine and the *left* pelvis. Beginning February 3, 1988, the licensee commenced treating the patient with cobalt-60 with a prescribed dose of 5000 rads to the spine (20 treatments of 250 rads each) and 4000 rads to the pelvis (20 treatments of 200 rads each).

On February 15, after 10 treatments totaling 2000 rads, the Dosimetrist became suspicious that an error had been made and that the wrong side of the patient's pelvis (the right side) had been treated. This was confirmed on February 16 by the Radiation Oncologist. The patient and referring physician were notified, and treatment on the left side of the pelvis was begun the following day.

In evaluating the event, the licensee said the patient had "documented bone destuction of the dorsal spine and left pelvis, and therefore, it is most probable there is disease throughout all the pelvic areas. The patient also had reported right side pain prior to the therapeutic treatment. Therefore, the palliative dose given to the right pelvis, rather than having caused him harm, could be considered prophylactic treatment."

In a report to NRC Region III dated March 9, the licensee said it was unclear whether the right-side treatment was "inadvertent or a conscious decision due to a misread of the bone scan." According to the referring physician, the patient exhibited no adverse aftereffects as a result of the misadministration.

Cause or Causes—The event is attributed to personnel errors and inadequate procedures. The radiation therapist had prescribed treatment to the dorsal spine and left pelvis. However, a therapy technologist set the patient up and marked the right pelvis. Neither the physicist, who performed the dose calculations, nor the chief technologist, who performed the treatment, noted the discrepancy between the treatment plan and the prescription. In addition, the dosimetrist, while performing a weekly chart check, failed to notice the error. About 10 days later, the dosimetrist again performed a chart check and noticed the discrepancy. She brought this to the attention of the physicist, who then discussed it with the radiation therapist. Treatment to the right pelvis was terminated at 2000 rads.

Actions Taken To Prevent Recurrence

Licensee—The licensee agreed to develop and implement procedures which require its staff to thoroughly review all aspects of therapy prescriptions and treatment parameters when the following events occur: (1) during the initial dose calculations, (2) just prior to initial treatment, and (3) during weekly chart checks.

NRC—A region-based inspector went to the hospital to review the incident on March 3 and 4, 1988. The NRC also retained an NRC medical consultant to review the misadministration. In the meantime, Region III conferred with the licensee on corrective action, and the licensee agreed to the above procedural changes. In a letter confirming the licensee's course of action dated March 10, 1988, Region III also requested that the procedural changes be formalized as a license amendment.

On April 14, 1988, a Notice of Violation was issued to the licensee; the therapy misadministration had not been reported to the NRC Regional Office until seven days after discovery, contrary to 10 CFR 35.33(a) which requires telephone notification within 24 hours.

88-9 Significant Widespread Breakdown in Radiation Safety Program at Case Western Reserve University Research Laboratories

One of the AO examples notes that serious deficiency in management or procedural controls in major areas can be considered an abnormal occurrence. In addition, one of the general AO criteria notes that a moderate release of radioactive material licensed by or otherwise regulated by the Commission can be considered an abnormal occurrence.

Date and Place—This occurrence addresses licensee performance over a period of time until February 26, 1988, when the NRC proposed imposing a $10,000 fine on Case Western Reserve University, Cleveland, Ohio.

Nature and Probable Consequences—The proposed fine was for numerous violations of NRC requirements in the licensee's radiation safety program for its research laboratories, indicating a significant breakdown in its management control program. The violations were in the licensee's research programs, not medical care and treatment of patients. The circumstances associated with the enforcement action are as follows.

On November 8, 1987, the NRC Region III office received a news media inquiry concerning the radioactive contamination of a research laboratory at Rainbow Babies and Children's Hospital in Cleveland, Ohio. The laboratory, although located at the hospital, was under the NRC license of Case Western Reserve University. Telephone discussions on November 9, 1987 with the licensee determined that a licensee consultant had identified tritium and carbon-14 contamination in the laboratory (Diabetes Laboratory) and that it was being decontaminated.

It was learned later, through subsequent telephone conversations with the licensee, that the contamination in the laboratory was more widespread than initially found. On November 17, 1987, the NRC began an inspection to review the circumstances of the contamination and to detemine if the problems associated with the laboratory

were indicative of additional problems at other licensee laboratories.

The initial and subsequent NRC inspections during November and December 1987 identified about 20 violations of NRC requirements, involving the training of laboratory personnel, radiation safety practices, and control and oversight of the laboratories using radioactive materials. Several of the violations (i.e., failure to calibrate radiation survey instruments, failure to perform a contamination survey, failure to perform leak tests of sealed radiation sources, and evidence of food and beverage consumption in laboratories) were similar to violations identified during a May 1986 NRC inspection at the licensee's facilities. Therefore, the licensee's corrective actions, taken following the 1986 inspection, were insufficient to prevent a recurrence of the violations.

Based on the inspection findings, it appeared that the University was unable to keep track of the number of laboratories engaged in licensed activities, was not controlling the required training of workers handling of radioactive materials, and was unable, through its radiation safety committee, to assure compliance with NRC requirements and license commitments. The latter became evident when the University found it necessary to contract with an outside consultant to perform required radiation surveys and audits which the University radiation staff could not complete in a timely manner. (It was a survey performed by the consultant which initially identified the contamination of the Diabetes Laboratory.)

In regard to the Diabetes Laboratory, the inspection indicated that no single incident appeared to have contributed to the contamination; rather the widespread, low-level contamination in the laboratory was caused by inadequate handling procedures (the technicians had not been adequately trained) and a lack of contamination surveys. There was no evidence that any workers or members of the public received a significant radiation exposure as a result of the contamination incident or of the violations found in the licensee's radiation safety program. Bioassay tests on the two Diabetes Laboratory technicians showed no detectable indication of ingestion or inhalation of radioactive material.

Cause or Causes—The failure to adequately correct past violations identified in a May 1986 inspection, as well as the numerous violations identified in the November–December 1987 inspections, demonstrated a serious, widespread breakdown in the management of the licensee's radiation safety program.

Actions Taken To Prevent Recurrence

Licensee—The licensee conformed to the various NRC actions described below. Following suspension of all NRC-licensed work (which affected about 350 laboratories), the licensee retained an interim Radiation Safety Officer, provided training to laboratory workers, and expanded the work of its consultant to review all laboratories for compliance with University and NRC requirements.

Extensive programmatic changes were made to the licensee's radiation safety program. Based on these changes, on December 8, 1987 the NRC authorized the gradual lifting of the suspension as each laboratory was checked and found to comply with NRC requirements. By mid-February 1988, work had been permitted to resume in all laboratories, except for the Diabetes Laboratory. The latter laboratory required final decontamination work before its suspension could be lifted.

During March 1988, the licensee hired a new Radiation Safety Officer to oversee NRC-licensed activities.

NRC—When the initial inspection revealed violations of NRC requirements, NRC Region III issued a Confirmatory Action Letter on November 20, 1987, documenting the University's agreement to accelerate its radiation survey program and to direct each laboratory supervisor to assure that the requirements were being followed.

Based on further inspection findings, a second Confirmatory Action Letter was issued on November 25, 1987, confirming the suspension of NRC-licensed work.

At the time work was authorized to resume on December 8, 1987, the NRC issued a license amendment to include the modifications and improvements to the radiation safety program adopted by the licensee.

On February 26, 1988, the NRC issued to the licensee a Notice of Violation Proposed Imposition of Civil Penalty in the amount of $10,000 for the numerous violations identified during the inspections. The inspection reports were also enclosed. The violations were categorized as Severity Level II (on a scale in which the most significant and least significant are categorized as Severity Levels I and V, respectively). The base value of a civil penalty for a Severity Level II violation is $4,000. This was increased to $10,000 because of the licensee's poor prior performance in their radiation safety program and the failure to take adequate corrective actions subsequent to the identification of violations during the most recent events. The licensee has paid the civil penalty.

The NRC will continue to monitor the licensee's performance through periodic inspections.

Dated at Rockville, MD, this 9th day of August 1988.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 88-18285 Filed 8-11-88; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-312]

Sacramento Municipal Utility District; Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR-54 issued to the Sacramento Municipal Utility District (the Licensee) for operation of the Rancho Seco Nuclear Generating Station located in Sacramento County, California.

The amendment would revise the Technical Specifications (TS) relating to Section 6.0, Administrative Controls, by removing the organization charts from the Technical Specification. The proposed amendment was requested by letter dated July 1, 1988.

Prior to issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the request for amendment involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. These three criteria are discussed in detail below.

(1) The NRC staff finds that the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated because removal of the organization charts from the Technical

Specifications is administrative in nature and does not affect plant operations or the number of members, composition, or function of the Plant Review Committee. As in the past, the NRC will continue to be informed of organizational changes through other required controls. The Code of Federal Regulations, 10 CFR Part 50.34(b)(5)(i), requires that the applicant's organizational structure be included in the Updated Safety Analysis Report (USAR). As required by 10 CFR 50.71(e), the licensee submits annual revisions to the USAR.

(2) The NRC staff finds that the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated becasue there is no physical alteration to any plant system, nor is there a change in the method in which any safety related system performs its function. The propsed changes are administrative in nature and, therefore, do not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) The NRC staff finds that because the proposed revision is administrative in nature, it will not reduce any margin of safety.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Comments should be addressed to the Rules and Procedures Branch, Office of Administration and Resources Managment, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room P-216, 7920 Norfolk Avenue, Bethesda, Maryland from 8:15 a.m. to 5.00 p.m. Copies of written comments may be examined at the NRC Public Document Room, 1717 H Street NW., Washington, DC. The filling of requests for hearing and petitions for leave to intervene is discussed below.

By September 12, 1988, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to pariticipate as a party in the proceeding must file a written request for hearing or petition for leave to intervene. Requests for hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Procedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition should specifically explan the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's proprety, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable speificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to persent evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene shall be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC, 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street NW., Washington, DC, by the above date. If petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner or representative for the petitioner promptly inform the Commission by a toll-free telephone call to Western Union at 1-800-325-6000 (in Missouri 1-800-342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message to George W. Knighton: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of the **Federal Register** notice. A copy of the petition should also be sent to the Office of General Counsel, U.S. Nuclear Regulatory Commission, DC 20555, and to David S. Kaplan, Sacramento

Municipal Utility District, 6201 S Street, P.O. Box 15830, Sacramento, California 95813.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board, that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated July 1, 1988, which is available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, DC and at the Sacramento City-County Library, 828 I Street, Sacramento, California 95814.

Dated at Rockville, Maryland, this 8th day of August, 1988.

For the Nuclear Regulatory Commission.

George Kalman,

Project Manager, Project Directorate V, Division of Reactor Projects—III, IV, V and Special Projects, Office of Nuclear Regulation.

[FR Doc. 88-18286 Filed 8-11-88; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-397]

Washington Public Power Supply System; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (Commission) has issued Amendment No. 62 to Facility Operating License No. NPF-21, issued to Washington Public Power Supply System (the licensee), which revised the Technical Specifications for operation of the Nuclear Project No. 2, located in Benton County, Washington.

The amendment was effective as of the date of issuance.

The amendment (1) revises limiting conditions for operation and instrumentation setpoints in the technical specifications to allow the operation of WNP-2 up to a power level of 75% power with one recirculation loop operating to the design burnup of the reload fuel of 35,000 MWD/MT bundle outage; (2) makes revisions to related sections of the technical specifications to improve clarity, and (3) adds a new section on power/flow instability and moves the specification addressing flux noise from the section on instrumentation to the section on power distribution limits.

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 1, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment and Opportunity for Hearing in connection with this action was published in the **Federal Register** on May 10, 1988 (53 FR 16605). No request for a hearing or petition for leave to intervene was filed following this notice.

The Commission has prepared an Environmental Assessment related to the action and has determined that an environmental impact statement will not be prepared and that issuance of this amendment will have no significant adverse effect on the quality of the human environment.

For further details with respect to the action see (1) the application for amendment dated March 7, 1988 (G02-88-053), as supplemented by letters dated March 7, 1988 (G02-88-054) and May 13, 1988 (G02-88-116), (2) Amendment No. 62 to License No. NPF-21, (3) the Commission's related Safety Evaluation and (4) the Commission's Environmental Assessment. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, DC 20555, and at the Richland City Library, Swift and Northgate Streets, Richland, Washington 99352. A copy of items (2), (3) and (4) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects III, IV, V and Special Projects.

Dated at Rockville, Maryland, this 5th day of August, 1988.

For The Nuclear Regulatory Commission.

Robert B. Samworth,

Senior Project Manager, Project Directorate V, Division of Reactor Projects—III, IV, V and Special Projects, Office of Nuclear Reactor Regulation.

[FR Doc. 88-18287 Filed 8-11-88; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-25980; File No. SR-PHLX-88-12]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to Floor Broker Transactions in Their Customer Accounts

On March 24, 1988, the Philadelphia Stock Exchange, Inc. ("PHLX" or "Exchange") submitted to the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b-4 thereunder,[2] a proposed rule change that clarifies that all persons employed on the PHLX trading floor in association with a Member or Participant, other than Registered Options Traders ("ROTs") and Specialists, are prohibited form initiating trades in PHLX options in their personal customer accounts while on the floor. The proposal was subsequently amended on July 22, 1988.[3]

The proposed rule change was noticed in Securities Exchange Act Release No. 25564 (April 8, 1988), 53 FR 12740 (April 18, 1988). No comments were received on the proposed rule change.

The purpose of the rule change is to make explicit the applicability of section 11(a) of the Act [4] to PHLX floor brokers and other options floor personnel. Under section 11(a) it is:

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[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b-4 (1986).

[3] See SR-PHLX-12, Amendment No. 1, submitted on July 22, 1988. The proposed rule, as amended, reads:

All persons employed on the trading floor in association with a Member or Participant, other than ROTs and Specialists, are prohibited from initiating trades in PHLX options in their customer accounts while on the floor. A Member or Participant firm which accepts an order for the customer account of such a person must process the order through the channels it normally provides for its other customer orders. When such an order is received on the floor, it may not be handled by any person associated or affiliated with such person or any person with a beneficial interest in the account. Once such a person has placed an order for his/her customer account in an option, that person is prohibited from brokering orders in that option until such order has been executed or cancelled. This provision shall not apply to any transaction permissible under section 11(a)(1) of the Securities Exchange Act of 1934.

Violations of the Rule would result in a $100 fine for the first occurrence and sanctions for additional violations thereafter would be within the Business Conduct Committee's discretion

[4] 15 U.S.C. 78k(a) (1982).

unlawful for any member of a national securities exchange to effect any transaction on such exchange for its own account, the account of an associated person, or an account with respect to which it or an associated person thereof exercises investment discretion.

Sections 11(a)(1)(A)–(H) then provide eight statutory exemptions from the trading restrictions imposed by section 11(a). Notwithstanding the prior and ongoing applicability of section 11(a) to all Exchange Members and Participants, the proposed rule change would impose identical restrictions on Exchange Member personnel. The Rule specifically prohibits persons employed on the trading floor in association with Members or Participants, other than ROTs and Specialists, from trading in their personal accounts while on the floor and it contains exceptions consistent with section 11(a).

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6.[5] Specifically, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act because it promotes just and equitable principles of trade and it is designed to prevent fraudulent and manipulative acts and practices by eliminating any trading advantage to those persons employed on the trading floor, other than ROTs and Specialists, due to their proximity to the trading floor. Moreover, because the proposed rule change is identical in operation to section 11(a) of the Act, it is enforcing compliance with a provision of the Act by PHLX members and persons associated with its members, and, therefore, is consistent with section 6(b)(1) of the Act.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[6] that the proposed rule change (SR-PHLX-88-12) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

Dated: August 8, 1988.

Jonathan G. Katz,

Secretary.

FR Doc. 88-18299 Filed 8-11-88; 8:45 am]

BILLING CODE 8010-01-M

[5] 15 U.S.C. 78f (1982).

[6] 15 U.S.C. 78s(b)(2) (1982).

[7] 17 CFR 200.30-3(a)(12) (1986).

SMALL BUSINESS ADMINISTRATION

[License No. 02/02-0361]

Wood River Capital Corp.; Filing of an Application for Approval of a Conflict of Interest Transaction

Notice is hereby given that Wood River Captial Corporation (Wood River), 645 Madison Avenue, New York, New York 10022, a Federal licensee under the Small Business Investment Act of 1958, as amended (the Act), has filed an application with the Small Business Administration (SBA) pursuant to section 312 of the Act and covered by § 107.903 of the SBA Rules and Regulations (the Regulations) governing Small Business Investment Companies (13 CFR 107.903 (1988)) for approval of a conflict of interest transaction falling within the scope of the above sections of the Act and the Regulations.

Subject to such approval Wood River proposes to provide funds to Westland Development Fund, Ltd. (Westland) for the purposes of subdividing land, developing buildings, and rehabilitating properties in the Greater Los Angeles area.

The proposed financing is brought within the purview of § 107.903(b)(1) of the Regulations because Mr. John V. Tunney is one of the general partners in Westland and is a director of The Prospect Group, Inc., which owns all of the issued and outstanding capital stock of Wood River. Westland is considered to be an associate of Wood River as defined by § 107.3 of the Regulations.

Notice is further given that any person may, not later than 15 days from the date of publication of the Notice, submit written comments on the proposed transaction to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street, NW., Washington, DC 20416.

A copy of this Notice shall be published, in accordance with § 107.903(e) of the Regulations, in a newspaper of general circulation in Los Angeles, California.

Robert G. Lineberry,

Deputy Associate Administrator for Investment.

Dated: August 3, 1988.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

[FR Doc. 88-18309 Filed 8-11-88; 8:45 am]

BILILNG CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Palm Springs Municipal Airport, Palm Springs, CA; Approval of Noise Compatibility Program

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the noise compatibility program submitted by the city of Palm Springs under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96-193) and 14 CFR Part 150. These findings are made in recognition of the description of federal and non-federal responsibilities in Senate Report No. 96-52 (1980). On August 24, 1987, the FAA determined that the noise exposure maps submitted by the city of Palm Springs under Part 150 were in compliance with applicable requirements. On May 23, 1988, the Administrator approved the Palm Springs Municipal Airport noise compatibility program. All but one of the recommendations of the program were approved.

EFFECTIVE DATE: The effective date of the FAA's approval of the Palm Springs Municipal Airport noise compatibility program is May 23, 1988.

FOR FURTHER INFORMATION CONTACT: Thomas J. Conley, Environmental Protection Specialist, AWP-611.3, Federal Aviation Administration, Western-Pacific Region, P.O. Box 92007, World Way Postal Center, Los Angeles, California 90009, (213) 297-1621. Documents reflecting this FAA action may be reviewed at this same location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the noise compatibility program for the Palm Springs Municipal Airport, effective May 23, 1988.

Under section 104(a) of the Aviation Safety and Noise Abatement Act of 1979, (hereinafter referred to as "The Act"), an airport operator who has previously submitted a noise exposure map may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible land uses within the area covered by the noise exposure maps. The Act requires such programs to be developed on consultation with interested and affected parties including local

communities government agencies, airport users, and FAA personnel.

Each airport noise compatibility program developed in accordance with Federal Aviation Regulations (FAR) Part 150 is a local program, not a federal program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measures should be recommended for action. The FAA's approval or disapproval of FAR Part 150 program recommendations is measured according to standards expressed in Part 150 and the Act and is limited to the following determinations:

A. The noise compatibility program was developed in accordance with the provisions and procedures of FAR Part 150;

B. Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

C. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

D. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of navigable and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport noise compatibility program are delineated in FAR Part 150, § 150.5.

Approval is not a determination concerning the acceptability of land uses under federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environment assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where Federal funding is sought, requests for project grants must be submitted to the FAA Airports Regional Office in Hawthorne, California.

The city of Palm Springs submitted to the FAA on February 2, 1987, the noise exposure maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from 1986 through 1991. The Palm Springs Municipal Airport noise exposure maps were determined by FAA to be in compliance with applicable requirements on August 24, 1987. Notice of this determination was published in the **Federal Register** on September 30, 1987.

The Palm Springs Municipal Airport study contains a proposed noise compatibility program comprised of actions designed for phased implementation by airport management and adjacent jurisdictions from the date of study completion to the year 1991. It was requested that the FAA evaluate and approve this material as a noise compatibility program as described in section 104(b) of the Act. The FAA began its review of the program on November 30, 1987, and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained fifteen proposed actions for noise mitigation on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR Part 150 have been satisfied. The overall program, therefore, was approved by the Administrator effective May 23, 1988.

Approval was granted for all but one of the specific program elements.

These determinations are set forth in detail in the Record of Approval endorsed by the Administrator on May 23, 1988. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the Administrative Offices of the Palm Springs Municipal Airport.

Issued in Hawthorne, California, on June 10, 1988.

Clyde DeHart, Jr.,

Acting Director.

[FR Doc. 88-16271 Filed 8-11-88; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Office of the Secretary

[Department Circular—Public Debt Series—No. 20-88]

Treasury Notes of August 15, 1991, Series T-1991

Washington, August 4, 1988.

1. Invitation for Tenders

1.1. The Secretary of the Treasury, under the authority of Chapter 31 of Title 31, United States Code, invites tenders for approximately $11,000,000,000 of United States securities, designated Treasury Notes of August 15, 1991, Series T-1991 (CUSIP No. 912827 WM O), hereafter referred to as Notes. The Notes will be sold at auction, with bidding on the basis of yield. Payment will be required at the price equivalent of the yield of each accepted bid. The interest rate on the Notes and the price equivalent of each accepted bid will be determined in the manner described below. Additional amounts of the Notes may be issued to Government accounts and Federal Reserve Banks for their own account in exchange for maturing Treasury securities. Additional amounts of the Notes 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 Notes will be dated August 15, 1988, and will accrue interest from that date, payable on a semiannual basis on February 15, 1989, and each subsequent 6 months on August 15 and February 15 through the date that the principal becomes payable. They will mature August 15, 1991, and will not be subject to call for redemption prior to maturity. In the event any payment date is a Saturday, Sunday, or other nonbusiness day, the amount due will be payable (without additional interest) on the next business day.

2.2. The Notes are subject to all taxes imposed under the Internal Revenue Code of 1954. The Notes are exempt from all taxation now or hereafter imposed on the obligation or interest thereof by any State, any possession of the United States, or any local taxing authority, except as provided in 31 U.S.C. 3124.

2.3. The Notes will be acceptable to secure deposits of Federal public monies. They will not be acceptable in payment of Federal taxes.

2.4. The Notes will be issued only in book-entry form in denominations of

$5,000, $10,000, $100,000, and $1,000,000, and in multiples of those amounts. They will not be issued in registered definitive or in bearer form.

2.5. The Department of the Treasury's general regulations governing United States securities, i.e., Department of the Treasury Circular No. 300, current revision (31 CFR Part 306), as to the extent applicable to marketable securities issued in book-entry form, and the regulations governing book-entry Treasury Bonds, Notes, and Bills, as adopted and published as a final rule to govern securities held in the *Treasury Direct* Book-Entry Securities System in 51 FR 18260, *et seq.* (May 16, 1986), apply to the Notes offered in this circular.

3. Sale Procedures

3.1. Tenders will be received at Federal Reserve Banks and Branches and at the Bureau of the Public Debt, Washington, DC 20239–1500, prior to 1:00 p.m., Eastern Daylight Saving time, Tuesday, August 9, 1988. Noncompetitive tenders as defined below will be considered timely if postmarked no later than Monday, August 8, 1988, and received no later than Monday, August 15, 1988.

3.2. The par amount of Notes bid for must be stated on each tender. 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%. Fractions may not be used. Noncompetitive tenders must show the term "noncompetitive" on the tender form in lieu of a specified yield.

3.3. A single bidder, as defined in Treasury's single bidder guidelines, shall not submit noncompetitive tenders totaling more than $1,000,000. A noncompetitive bidder may not have entered into an agreement, nor make an agreement of purchase or sell or otherwise dispose of any noncompetitive awards of this issue prior to the deadline for receipt of tenders.

3.4. 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 are on the list of reporting dealers published by the Federal Reserve Bank of New York, may submit tenders for accounts of customers if the names of the customers and the amount for each customer are furnished. Others are permitted to submit tenders only for their own account.

3.5. Tenders for their own account will be received without deposit 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 all others must be accompanied by full payment for the amount of Notes applied for, or by a guarantee from a commercial bank or a primary dealer of 5 percent of the par amount applied for.

3.6. Immediately after the deadline for receipt of tenders, 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, an interest rate will be established, at 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 99.250. That stated rate of interest will be paid on all of the Notes. 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.

3.7. Competitive bidders will be advised of the acceptance of their bids. Those submitting noncompetitive tenders will be notified only if the tender is not accepted in full, or when the price at the average yield 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 Notes 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 the Notes allotted 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 Notes allotted to institutional investors and to others whose tenders are accompanied by a guarantee as provided in section 3.5 must be made or completed on or before Monday, August 15, 1988. 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 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, August 11, 1988. In addition, Treasury Tax and Loan Note Option Depositaries may make payment for the Notes allotted for their own accounts and for accounts of customers by credit to their Treasury Tax and Loan Note Accounts on or before Monday, August 15, 1988. When payment has been submitted with the tender and the purchase price of the Notes allotted is over par, settlement for the premium must be completed timely, as specified above. When payment has been submitted with the tender and the purchase price is under par, the discount will be remitted to the bidder.

5.2. In every case where full payment has not been completed on time, an amount of up to 5 percent of the par amount of Notes allotted shall, at the discretion of the Secretary of the Treasury, be forfeited to the United States.

5.3. Registered definitive securities tendered in payment for the Notes allotted and to be held in *Treasury Direct* are not required to be assigned if the inscription on the registered definitive security is identical to the registration of the note being purchased.

In any such case, the tender form used to place the Notes allotted in *Treasury Direct* must be completed to show all the information required thereon, or the *Treasury Direct* account number previously obtained.

6. General Provisions

6.1. As fiscal agents of the United States, Federal Reserve Banks are authorized, as directed by the Secretary of the Treasury, to receive tenders, to make allotments, to issue such notices as may be necessary, to receive payment for, and to issue, maintain, service, and make payment on the Notes.

6.2. The Secretary of the Treasury may at any time supplement or amend provisions of this circular if such supplements or amendments do not adversely affect existing rights of holders of the Notes. Public announcement of such changes will be promptly provided.

6.3. The Notes issued under this circular shall be obligations of the United States, and, therefore, the faith of the United States Government is pledged to pay, in legal tender, principal and interest on the Notes.

Gerald Murphy,

Fiscal Assistant Secretary.

[FR Doc. 88-18234 Filed 8-9-88; 10:43 am]

BILLING CODE 4810-40-M

[Department Circular—Public Debt Series—No. 21-88]

Treasury Notes of August 15, 1988, Series C-1998

Washington, August 4, 1988.

1. Invitation for Tenders

1.1. The Secretary of the Treasury, under the authority of Chapter 31 of Title 31, United States Code, invites tenders for approximately $11,000,000,000 of United States securities, designated Treasury Notes of August 15, 1998, Series C-1998 (CUSIP No. 912827 WN8), hereafter referred to as Notes. The Notes will be sold at auction, with bidding on the basis of yield. Payment will be required at the price equivalent of the yield of each accepted bid. The interest rate on the Notes and the price equivalent of each accepted bid will be determined in the manner described below. Additional amounts of the Notes may be issued to Government accounts and Federal Reserve Banks for their own account in exchange for maturing Treasury securities. Additional amounts of the Notes 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 Notes will be dated August 15, 1988, and will accrue interest from that date, payable on a semiannual basis on February 15, 1989, and each subsequent 6 months on August 15 and February 15 through the date that the principal becomes payable. They will mature August 15, 1998, and will not be subject to call for redemption prior to maturity. In the event any payment date is a Saturday, Sunday, or other nonbusiness day, the amount due will be payable (without additional interest) on the next business day.

2.2. The Notes are subject to all taxes imposed under the Internal Revenue Code of 1954. The Notes are exempt from all taxation now or hereafter imposed on the obligation or interest thereof by any State, any possession of the United States, or any local taxing authority, except as provided in 31 U.S.C. 3124.

2.3. The Notes will be acceptable to secure deposits of Federal public monies. They will not be acceptable in payment of Federal taxes.

2.4. The Notes will be issued only in book-entry form in denominations of $1,000, $5,000, $10,000, $100,000, and $1,000,000, and in multiples of those amounts. They will not be issued in registered definitive or in bearer form.

2.5. A Note may be held in its fully constituted form or it may be divided into its separate Principal and Interest Components and maintained as such on the book-entry records of the Federal Reserve Banks, acting as fiscal agents of the United States. The provisions specifically applicable to the separation, maintenance, transfer, and reconstitution of Principal and Interest Components are set forth in section 6 of this circular. Subsections 2.1. through 2.4. of this section are descriptive of Notes in their fully constituted form; the description of the separate Principal and Interest components is set forth in section 6 of this circular.

2.6. The Department of the Treasury's general regulations governing United States securities, i.e., Department of the Treasury Circular No. 300, current revision (31 CFR Part 306), as to the extent applicable to marketable securities issued in book-entry form, and the regulations governing book-entry Treasury Bonds, Notes, and Bills, as adopted and published as a final rule to govern securities held in the *Treasury Direct* Book-Entry Securities System in 51 FR 18260, *et seq.* (May 16, 1986), apply to the Notes offered in this circular.

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. 20239-1500, prior to 1:00 p.m., Eastern Daylight Saving time, Wednesday, August 10, 1988. Noncompetitive tenders as defined below will be considered timely if postmarked no later than Tuesday, August 9, 1988, and received no later than Monday, August 15, 1988.

3.2. The par amount of Notes bid for must be stated on each tender. The minimum bid is $1,000, 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%. Fractions may not be used. Noncompetitive tenders must show the term "noncompetitive" on the tender form in lieu of a specified yield.

3.3. A single bidder, as defined in Treasury's single bidder guidelines, shall not submit noncompetitive tenders totaling more than $1,000,000. A noncompetitive bidder may not have entered into an agreement, nor make an agreement to purchase or sell or otherwise dispose of any noncompetitive awards of this issue prior to the deadline for receipt of tenders.

3.4. 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 are on the list of reporting dealers published by the Federal Reserve Bank of New York, may submit tenders for accounts of customers if the names of the customers and the amount for each customer are furnished. Others are permitted to submit tenders only for their own account.

3.5. Tenders for their own account will be received without deposit 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 all others must be accompanied by full payment for the amount of Notes applied for, or by a guarantee from a commercial bank or a primary dealer of 5 percent of the par amount applied for.

3.6. Immediately after the deadline for receipt of tenders, 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 yeilds, 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, an interest rate will be established, at a ⅛ of one percent increment, which results in an equivalent average accepted price close to 100.000 and a lowest acepted price above the original issue discount limit of 97.500. That stated rate of interest will be paid on all of the Notes. 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.

3.7. Competitive bidders will be advised of the acceptance of their bids. Those submitting noncompetitive tenders will be notified only if the tender is not accepted in full, or when the price at the average yield 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 Notes 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 the Notes allotted 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 Notes allotted to institutional investors and to others whose tenders are accompanied by a guarantee as provided in section 3.5. must be made or completed on or before Monday, August 15, 1988. 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 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, August 11, 1988. In addition, Treasury Tax and Loan Note Option Depositaries may make payment for the Notes allotted for their own accounts and for accounts of customers by credit to their Treasury Tax and Loan Note Accounts on or before Monday, August 15, 1988. When payment has been submitted with the tender and the purchase price of the Notes allotted is over par, settlement for the premium must be completed timely, as specified above. When payment has been submitted with the tender and the purchase price is under par, the discount will be remitted to the bidder.

5.2. In every case where full payment has not been completed on time, an amount of up to 5 percent of the par amount of Notes allotted shall, at the discretion of the Secretary of the Treasury, be forfeited to the United States.

5.3. Registered definitive securities tendered in payment for the Notes allotted and to be held in *Treasury Direct* are not required to be assigned if the inscription on the registered definitive security is identical to the registration of the Note being purchased. In any such case, the tender form used to place the Notes allotted in *Treasury Direct* must be completed to show all the information required thereon, or the *Treasury Direct* account number previously obtained.

6. Separability of Principal and Interest

6.1. Under the Treasury's STRIPS Program (Separate Trading of Registered Interest and Principal of Securities), a Note may be divided into its separate components and maintained as such on the book-entry records of the Federal Reserve Banks, acting as Fiscal Agents of the United States. The separate STRIPS components are: each future semiannual interest payment (referred to as an Interest Component) and the principal payment (referred to as the Principal Component). Each Interest Component and the Principal Component shall have an identifying designation and CUSIP number, which are set forth in Attachment A to this circular.

6.2. Attachment A also provides the payable dates for the separate components. In the event any payment date is a Saturday, Sunday, or other nonbusiness day, the amount due will be payable (without additional interest) on the next business day.

6.3. For a Note to be separated into the components described in section 6.1., the par amount of the Note must be in an amount which, based on the stated interest rate of the Note, will produce a semiannual interest payment of $1,000 or a multiple of $1,000. Attachment B to this circular provides the minimum par amounts required to separate a security at various interest rates, as well as the interest payments corresponding to those minimum par amounts. Par amounts greater than the minimum amount must be in multiples of that amount. The minimum par amount for this offering will be provided in the public announcement of the amount and yield range of accepted bids.

6.4. A Note may be separated into its components at any time from the issue date until maturity. A request for separation must be made to the Federal Reserve Bank maintaining the account for the Notes. Once a Note has been separated into its components, the components may be maintained and transferred in multiples of $1,000.

6.5. Interest Components and Principal Components in multiples of $1,000 will be acceptable to secure deposits of Federal public monies. They will not be acceptable in payment of Federal taxes.

6.6. Interest and Principal Components of separated securities may be reconstituted, i.e., restored to their fully constituted form, on the book-entry records of the Federal Reserve Banks. A Principal Component and all related unmatured Interest Components, in the appropriate minimum or multiple amounts previously announced, must be submitted together for reconstitution.

6.7. Detached physical interest coupons, coupons held under the CUBES Program, or cash payments may not be substituted for missing Interest or Principal Components. Any reconstitution request which does not comprise all of the necessary STRIPS components in the appropriate amounts will not be accepted.

6.8. The book-entry transfer of each Interest Component and Principal Component included in a reconstitution

transaction will be subject to the fee schedule generally applicable to transfers of book-entry Treasury securities.

6.9. Unless otherwise provided in this offering circular, the Department of the Treasury's general regulations governing United States securities apply to the Notes separated into their components.

7. General Provisions.

7.1. As fiscal agents of the United States, Federal Reserve Banks are authorized, as directed by the Secretary of the Treasury, to receive tenders, to make allotments, to issue such notices as may be necessary, to receive payment for, and to issue, maintain, service, and make payment on the Notes.

7.2. The Secretary of the Treasury may at any time supplement or amend provisions of this circular if such supplements or amendments do not adversely affect existing rights of holders of the Notes. Public announcement of such changes will be promptly provided.

7.3. The Notes issued under this circular shall be obligations of the United States, whether held in the fully constituted form or as separate Interest and Principal Components, and, therefore, the faith of the United States Government is pledged to pay, in legal tender, principal and interest on the Notes.

7.4. Attachments A and B are incorporated as part of this circular.

Gerald Murphy,

Fiscal Assistant Secretary.

CUSIP Numbers and Designations for the Principal Component and Interest Components of Treasury Notes of August 15, 1998, Series C–1998, CUSIP No. 912827 WN 8

The Principal Component is designated (Interest Rate) Treasury Principal (TPRN) Series C–1998 due August 15, 1998, CUSIP No. 912820 AP 2.

INTEREST COMPONENTS

Designation	CUSIP No. 912833
Treasury Interest (TINT) due:	
Feb. 15, 1989	BD 1
Aug. 15, 1989	BE 9
Feb. 15, 1990	BF 6
Aug. 15, 1990	BG 4
Feb. 15, 1991	BH 2
Aug. 15, 1991	BJ 8
Feb. 15, 1992	BK 5
Aug. 15, 1992	BL 3
Feb. 15, 1993	BM 1
Aug. 15, 1993	BN 9
Feb. 15, 1994	BP 4
Aug. 15, 1994	BQ 2
Feb. 15, 1995	BR 0
Aug. 15, 1995	BS 8
Feb. 15, 1996	BT 6
Aug. 15, 1996	BU 3
Feb. 15, 1997	BV 1
Aug. 15, 1997	BW 9
Feb. 15, 1998	BX 7
Aug. 15, 1998	BY 5

ATTACHMENT B.—MINIMUM FACE AMOUNTS WHICH ARE MULTIPLES OF $1,000 REQUIRED IN ORDER TO PRODUCE INTEREST PAYMENTS THAT ARE MULTIPLES OF $1,000

Coupon (percent)	Minimum face (dollars)	Interest payment (dollars)	Coupon (percent)	Minimum face (dollars)	Interest payment (dollars)	Coupon (percent)	Minimum face (dollars)	Interest payment (dollars)
5.000	40,000.00	1,000.00	10.125	1,600,000.00	81,000.00	15.250	800,000.00	61,000.00
5.125	1,600,000.00	41,000.00	10.250	800,000.00	41,000.00	15.375	1,600,000.00	123,000.00
5.250	800,000.00	21,000.00	10.375	1,600,000.00	83,000.00	15.500	400,000.00	31,000.00
5.375	1,600,000.00	43,000.00	10.500	400,000.00	21,000.00	15.625	64,000.00	5,000.00
5.500	400,000.00	11,000.00	10.625	320,000.00	17,000.00	15.750	800,000.00	63,000.00
5.625	320,000.00	9,000.00	10.750	800,000.00	43,000.00	15.875	1,600,000.00	127,000.00
5.750	800,000.00	23,000.00	10.875	1,600,000.00	87,000.00	16.000	25,000.00	2,000.00
5.875	1,600,000.00	47,000.00	11.000	200,000.00	11,000.00	16.125	1,600,000.00	129,000.00
6.000	100,000.00	3,000.00	11.125	1,600,000.00	89,000.00	16.250	160,000.00	13,000.00
6.125	1,600,000.00	49,000.00	11.250	160,000.00	9,000.00	16.375	1,600,000.00	131,000.00
6.250	32,000.00	1,000.00	11.375	1,600,000.00	91,000.00	16.500	400,000.00	33,000.00
6.375	1,600,000.00	51,000.00	11.500	400,000.00	23,000.00	16.625	1,600,000.00	133,000.00
6.500	400,000.00	13,000.00	11.625	1,600,000.00	93,000.00	16.750	800,000.00	67,000.00
6.625	1,600,000.00	53,000.00	11.750	800,000.00	47,000.00	16.875	320,000.00	27,000.00
6.750	800,000.00	27,000.00	11.875	320,000.00	19,000.00	17.000	200,000.00	17,000.00
6.875	320,000.00	11,000.00	12.000	50,000.00	3,000.00	17.125	1,600,000.00	137,000.00
7.000	200,000.00	7,000.00	12.125	1,600,000.00	97,000.00	17.250	800,000.00	69,000.00
7.125	1,600,000.00	57,000.00	12.250	800,000.00	49,000.00	17.375	1,600,000.00	139,000.00
7.250	800,000.00	29,000.00	12.375	1,600,000.00	99,000.00	17.500	80,000.00	7,000.00
7.375	1,600,000.00	59,000.00	12.500	16,000.00	1,000.00	17.625	1,600,000.00	141,000.00
7.500	80,000.00	3,000.00	12.625	1,600,000.00	101,000.00	17.750	800,000.00	71,000.00
7.625	1,600,000.00	61,000.00	12.750	800,000.00	51,000.00	17.875	1,600,000.00	143,000.00
7.750	800,000.00	31,000.00	12.875	1,600,000.00	103,000.00	18.000	100,000.00	9,000.00
7.875	1,600,000.00	63,000.00	13.000	200,000.00	13,000.00	18.125	320,000.00	29,000.00
8.000	25,000.00	1,000.00	13.125	320,000.00	21,000.00	18.250	800,000.00	73,000.00
8.125	320,000.00	13,000.00	13.250	800,000.00	53,000.00	18.375	1,600,000.00	147,000.00
8.250	800,000.00	33,000.00	13.375	1,600,000.00	107,000.00	18.500	400,000.00	37,000.00
8.375	1,600,000.00	67,000.00	13.500	400,000.00	27,000.00	18.625	1,600,000.00	149,000.00
8.500	400,000.00	17,000.00	13.625	1,600,000.00	109,000.00	18.750	32,000.00	3,000.00
8.625	1,600,000.00	69,000.00	13.750	160,000.00	11,000.00	18.875	1,600,000.00	151,000.00
8.750	160,000.00	7,000.00	13.875	1,600,000.00	111,000.00	19.000	200,000.00	19,000.00
8.875	1,600,000.00	71,000.00	14.000	100,000.00	7,000.00	19.125	1,600,000.00	153,000.00
9.000	200,000.00	9,000.00	14.125	1,600,000.00	113,000.00	19.250	800,000.00	77,000.00
9.125	1,600,000.00	73,000.00	14.250	800,000.00	57,000.00	19.375	320,000.00	31,000.00

ATTACHMENT B.—MINIMUM FACE AMOUNTS WHICH ARE MULTIPLES OF $1,000 REQUIRED IN ORDER TO PRODUCE INTEREST PAYMENTS THAT ARE MULTIPLES OF $1,000—Continued

Coupon (percent)	Minimum face (dollars)	Interest payment (dollars)	Coupon (percent)	Minimum face (dollars)	Interest payment (dollars)	Coupon (percent)	Minimum face (dollars)	Interest payment (dollars)
9.250	800,000.00	37,000.00	14.375	320,000.00	23,000.00	19.500	400,000.00	39,000.00
9.375	64,000.00	3,000.00	14.500	400,000.00	29,000.00	19.625	1,600,000.00	157,000.00
9.500	400,000.00	19,000.00	14.625	1,600,000.00	117,000.00	19.750	800,000.00	79,000.00
9.625	1,600,000.00	77,000.00	14.750	800,000.00	59,000.00	19.875	1,600,000.00	159,000.00
9.750	800,000.00	39,000.00	14.875	1,600,000.00	119,000.00	20.000	10,000.00	1,000.00
9.875	1,600,000.00	79,000.00	15.000	40,000.00	3,000.00	20.125	1,600,000.00	161,000.00
10.000	20,000.00	1,000.00	15.125	1,600,000.00	121,000.00	20.250	800,000.00	81,000.00

[FR Doc. 88-18235 Filed 8-9-88; 10:43 am]
BILLING CODE 4910-40-M

Sunshine Act Meetings

Federal Register
Vol. 53, No. 156
Friday, August 12, 1988

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).

FEDERAL DEPOSIT INSURANCE CORPORATION

Changes 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. 552(e)(2)), notice is hereby given that at its closed meeting held at 2:30 p.m. on Tuesday, August 9, 1988, the Corporation's Board of Directors determined, on motion of Chairman L. William Seidman, seconded by Director C.C. Hope, Jr. (Appointive), concurred in by Director Robert L. Clarke (Comptroller of the Currency), that Corporation business required the addition to the agenda for consideration at the meeting, on less then seven days' notice to the public, of: (1) Matters relating to the Corporation's assistance agreements with certain insured banks; and (2) a discussion concerning deposit insurance coverage.

The Board further determined, by the same majority vote, that no earlier notice of these changes in the subject matter of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: August 10, 1988.

Federal Deposit Insurance Corporation.

Robert E. Feldmam,

Deputy Executive Secretary.

[FR Doc. 88-18349 Filed 8-10-88; 11:18 am]

BILLING CODE 6714-01-M

POSTAL SERVICE BOARD OF GOVERNORS

Vote To Close Meeting

At its meeting on August 1, 1988, the Board of Governors of the United States Postal Service voted unanimously to close to public observation its meeting scheduled for September 12, 1988, in Washington, DC. The members will consider a temporary mail classification change affecting certain second-class mail matter.

The meeting is expected to be attended by the following persons: Governors Alvarado, del Junco, Griesemer, Hall, Nevin, Pace, Ryan and Setrakian; Postmaster General Frank; Deputy Postmaster General Coughlin; Secretary to the Board Harris; and General Counsel Cox.

The Board determined that pursuant to section 552b(c)(3) of title 5, United States Code, and § 7.3(c) of Title 39, Code of Federal Regulations, discussion of this matter is exempt from the open meeting requirement of the Government in the Sunshine Act, (5 U.S.C. 552b(b)), because it is likely to disclose information in connection with proceedings under Chapter 36 of Title 39 (having to do with postal ratemaking, mail classification and changes in postal services), which is specifically exempted from disclosure by § 410(c)(4) of Title 39, United States Code.

The Board has determined further that pursuant to §552b(c)(10) of Title 5, United States Code, and § 7.3(j) of Title 39, Code of Federal Regulations, the discussion is exempt because it is likely to specifically concern the participation of the Postal Service in a civil action or proceeding involving a determination on the record after opportunity for a hearing. The Board further determined that the public interest does not require that the Board's discussion of the matter be open to the public.

In accordance with § 552b(f)(1) of Title 5, United States Code, and § 7.6(a) of Title 39, Code of Federal Regulations, the General Counsel of the United States Postal Service has certified that in his opinion the meeting may properly be closed to public observation pursuant to § 552b(c) (3) and (10) of Title 5 and § 410(c)(4) of Title 39, United States Code; and § 7.3 (c) and (j) of Title 39, Code of Federal Regulations.

Requests for information about the meeting should be addressed to the Secretary of the Board, David F. Harris, at (202) 268-4800.

David F. Harris,

Secretary.

Fred Eggleston,

Alternate Certifying Officer for the U.S. Postal Service.

[FR Doc. 88-18370 Filed 8-10-88; 1:19 pm]

BILLING CODE 7710-12-M

Corrections

Federal Register
Vol. 53, No. 156
Friday, August 12, 1988

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, and 1926

[Docket H-022D]

Hazard Communication

Correction

In the proposed rule document beginning on page 29822 in the issue of Monday, August 8, 1988, make the following correction:

On page 29856, in the third column, in the file line at the end of the document, "FR Doc. 88-17716" should read "88-17716(a)".

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 210

Federal Payments Made Through Financial Institutions by the Automated Clearing House Method

Correction

In proposed rule document 88-16707 beginning on page 28233 in the issue of Wednesday, July 27, 1988, make the following corrections:

1. On page 28233, in the third column, under **SUPPLEMENTARY INFORMATION**, in the second paragraph, in the 15th line, "financial" was misspelled; and in the 20th line, "institution" should read "instruction".

2. On page 28234, in the second column, in the first paragraph, in the fifth line "there" should read "their".

§ 210.2 [Corrected]

3. On page 28235, in the first column, in § 210.2, in the definition for "Recipient", in the second line "pubic" should read "public".

§ 210.11 [Corrected]

4. On the same page, in the third column, in § 210.11(b), in the 11th line, "beneficiary" should read "beneficiary's".

BILLING CODE 1505-01-D

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

Procurement List 1988 Addition

Correction

In notice document 88-17717 beginning on page 29510 in the issue of Friday, August 5, 1988, make the following correction:

On page 29511, in the first column, before the signature line, insert "Rod, Ground 5975-00-878-3791".

BILLING CODE 1505-01-D

federal register

Friday
August 12, 1988

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 341

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Combination Drug Products; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 76N-052G]

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Combination Drug Products

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products (drug products that contain more than one active ingredient and are used for the relief of symptoms such as nasal congestion, runny nose, coughing, watery eyes, sore throat, headache, and fever) are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal deals with cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products, general comments on the advance notice of proposed rulemaking, and comments on miscellaneous ingredients, as well as the conclusions and recommendations of the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products on the use of internal analgesic ingredients in cough-cold combination drug products, and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by December 12, 1988. Because of the length and complexity of this proposed regulation, the agency is allowing a period of 120 days for comments and objections instead of the normal 60 days. New data by August 14, 1989. Comments on the new data by October 12, 1989. Written comments on the agency's economic impact determination by December 12, 1988.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 1976 (41 FR 38312), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products, together with the recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in these drug classes. Interested persons were invited to submit comments by December 8, 1976. Reply comments in response to comments filed in the initial comment period could be submitted by January 7, 1977.

In a notice published in the **Federal Register** of March 21, 1980 (45 FR 18400), the agency advised that it had reopened the administrative record for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products to allow for consideration of data and information that had been filed in the Dockets Management Branch after the date the administrative record previously had officially closed. The agency concluded that any new data and information filed prior to March 21, 1980, should be available to the agency in developing a proposed regulation in the form of a tentative final monograph.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, (address above), after deletion of a small amount of trade secret information. Data and information received after the administrative record was reopened have also been put on display in the Dockets Management Branch.

In response to the advance notice of proposed rulemaking, 13 manufacturers, 2 manufacturers' associations, 41 consumers, 14 health care professionals, and 14 health care professional societies submitted general comments on cold, cough, allergy, bronchodilator, and antiasthmatic drugs. One manufacturer, 2 consumers, and 1 consumer group submitted comments on miscellaneous ingredients. Fifteen manufacturers, 2 manufacturers' associations, 4 consumers, 3 health care professionals, and 3 health care professional societies submitted comments on cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products. Copies of the comments received are on public display in the Dockets Management Branch.

FDA has issued the tentative final monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products in segments. This document on combination drug products, general issues, and miscellaneous ingredients is the sixth and final segment. The first segment, on anticholinergic drug products and expectorant drug products, was published in the **Federal Register** of July 9, 1982 (47 FR 30002). The second segment, on bronchodilator drug products, was published in the **Federal Register** of October 26, 1982 (47 FR 47520). The third segment, on antitussive drug products, was published in the **Federal Register** of October 19, 1983 (48 FR 48576). The fourth segment, on nasal decongestant drug products, was published in the **Federal Register** of January 15, 1985 (50 FR 2220), and the fifth segment, on antihistamine drug products, was published in the **Federal Register** of January 15, 1985 (50 FR 2200). Additionally, an amendment to the tentative final monograph for OTC antihistamine drug products was published in the **Federal Register** of August 24, 1987 (52 FR 31892).

The advance notice of proposed rulemaking, which was published in the **Federal Register** on September 9, 1976 (41 FR 38312), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the present document is designated in the OTC drug review regulations as a "tentative final monograph." Its legal status, however, is that of a proposed rule. This tentative final monograph would amend Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations in Part 341 (as set forth in the tentative final monograph on OTC anticholinergic drug products and expectorant drug products that was published in the **Federal Register** of July 9, 1982 (47 FR 30002)) in Subpart B, by adding new § 341.40; and in Subpart C, by adding new § 341.85. In this tentative final monograph (proposed rule) the FDA states for the first time its position on the establishment of a monograph for OTC cold, cough, allergy,

bronchodilator, and antiasthmatic combination drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products.

This proposal constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products, as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them. When the tentative final monograph for OTC anticholinergic drug products and expectorant drug products was published on July 9, 1982, no ingredients were classified in Category I; thus no ingredients were included in the active ingredient section under Part 341 of that monograph. Subsequently, data were submitted which support the effectiveness of guaifenesin as an expectorant. Because guaifenesin will be included as a monograph condition in § 341.18 of the final monograph for OTC expectorant drug products, to be published in a future issue of the **Federal Register**, combinations in this proposal containing an expectorant refer to § 341.18.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products (published in the **Federal Register** of September 9, 1976 (41 FR 38312)), the agency suggested that the conditions included in the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the **Federal Register** and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products will have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to safe and effective drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products. All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the **Federal Register** of August 9, 1972 (37 FR 16029) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

A. General Comments on Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products

1. One comment expressed concern about the impact of the OTC drug review. The comment felt that the review would remove certain cough-cold products from the OTC market and force consumers to see a physician just to obtain a prescription for cough-cold products, causing a financial drain on persons dependent on social security.

The purpose of the OTC drug review is to assure consumers that OTC drug products are safe and effective. The review will result in the removal of unsafe or ineffective drug products from the OTC market. Also, some products may be reformulated to contain ingredients that are found to be

generally recognized as safe and effective. Products already on the market which contain ingredients that are generally recognized as safe and effective will remain available to consumers. In addition, a number of drug products that have been available only by prescription are being changed to OTC status and will be more readily available to consumers. Thus, the OTC drug review will not result in a financial drain on persons dependent on a fixed income but will ensure that safe and effective OTC drug products are available for self-treatment of colds, coughs, allergy, and asthma.

2. Several comments questioned the legality of the procedures used to establish OTC drug monographs and contended that FDA does not have the authority to establish substantive rules. The comments requested that monographs be clearly identified as interpretive rather than substantive regulations.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464), and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).

3. One comment objected to the Panel's classification of "official drugs" in Category III. The comment contended that Congress has recognized the United States Pharmacopeia (USP) and the National Formulary (NF) as legal standards under the Federal Food, Drug, and Cosmetic Act (the act) and that the Committees on Scope of the Compendia have stated that their policy is "to select from among substances which possess medicinal power, those, the utility of which is most fully established and best understood. The value of the Compendia depends upon the fidelity with which they conform to the best medicinal knowledge of the day."

Formerly, articles judged to have medical merit were selected for inclusion in the USP and NF. USP XIX (1975) and NF XIV (1975) were the last editions of the compendia in which the articles were selected for inclusion on this basis. The USP and NF have now been combined (USP XX–NF XV, 1980) with the stated goal of setting standards relating to measurements of strength, quality and purity, packaging, etc. for "all" drugs that are in the marketplace (Ref. 1). This goal is also stated in the current edition of the USP XXI–NF XVI (Ref. 2). Thus, the current basis for inclusion of a drug in the combined compendia is whether it is marketed. The OTC Panel's review of drug ingredients is different from the USP and NF standards in that ingredients used in OTC drug products are evaluated for general recognition of safety and effectiveness in accordance with statutory authority set out in the act. A drug in the marketplace that has been labeled as meeting the USP or NF standards does not necessarily meet the FDA requirements relating to general recognition of safety and effectiveness, and to misbranding. Hence, a drug may meet USP or NF standards but still be classified as a Category II or Category III OTC drug.

References

(1) "The United States Pharmacopeia XX—National Formulary XV," United States Pharmacopeial Convention, Rockville, MD pp. xxxiv–xlii, 1980.

(2) "The United States Pharmacopeia XXI—National Formulary XVI," United States Pharmacopeial Convention, Rockville, MD, pp. xliv–xlv, 1985.

4. One comment stated that the agency's objections to various decisions made by the Panel should be based on more than just the referenced "AMA Drug Evaluations." The comment expressed the hope that the agency consulted the same source material that the Panel used, and recommended that the agency mention all of its sources when publishing decisions.

The comment's statements were in reference to the preamble to the Panel's report (41 FR 38312 to 38313), where the agency disagreed with the Panel's recommendations that three drugs (doxylamine succinate, promethazine hydrochloride, and diphenhydramine hydrochloride) that were previously available only by prescription be made available for OTC use.

The three ingredients mentioned above are discussed in the tentative final monograph for OTC antihistamine drug products. (See the **Federal Register** of January 15, 1985 (50 FR 2200) and August 24, 1987 (52 FR 31892).) In these documents, the agency has proposed a Category I classification for diphenhydramine hydrochloride and doxylamine succinate as an OTC antihistamine, and a Category III classification for promethazine hydrochloride. In the tentative final monograph for OTC antitussive drug products, the agency placed diphenhydramine hydrochloride in Category III as an antitussive (see the **Federal Register** of October 19, 1983; 48 FR 48581) and classified it as a nonmonograph ingredient in the final monograph for OTC antitussive drug products (see the **Federal Register** of August 12, 1987; 52 FR 30054). In those documents, references that were used to support decisions have been cited.

Many sources of information are available to and used by the agency in making decisions related to the OTC drug review. Such sources include data submitted to the panels, data submitted as comments to the agency, data in the literature, and data obtained from various computerized information retrieval systems which provide information on published literature, adverse drug reactions, poison control statistics, etc. The agency also uses the medical expertise of its staff in reaching decisions. This expertise includes the review of adverse drug reaction data that are incorporated into agency computerized information retrieval systems. This is especially done when prescription-to-OTC switches are involved, as in the situation discussed by the comment. Such information reviewed is regularly incorporated in the public administrative file for the applicable rulemaking.

5. Three comments stated that inactive chemicals, dyes (coloring), perfumes, flavorings, alcohol, and preservatives should not be in OTC drug products. One of the comments added that many adults and children are allergic to flavorings and colorings and contended that these additives serve no useful function and are added only for cosmetic purposes.

FDA does not agree that the inactive ingredients the comments describe should not be in OTC drug products. The agency recognizes that the use of such ingredients in OTC drug products is often important in securing consumer acceptance. Although they offer no particular therapeutic advantage, the use of these agents can be of considerable importance psychologically (Ref. 1). An OTC drug product that is rejected by consumers because of objectionable taste or appearance may be made acceptable by use of carefully selected coloring, flavoring, and diluting agents. If a safety problem with one of these agents is found to exist, the agency will take appropriate action, as, for example, in the case of the regulations adopted concerning sensitivity to the color

additive FD&C Yellow No. 5. In § 201.20 (21 CFR 201.20), the agency requires that all OTC and prescription drug products containing this agent declare its presence in labeling, using the names FD&C Yellow No. 5 and tartrazine. While not requiring that all inactive ingredients be listed in labeling, the agency urges manufacturers to list these ingredients voluntarily to assist consumers who may have allergies to some of these substances. (See also comment 20 below.)

Reference

(1) Gennaro, A.R., editor, "Remington's Pharmaceutical Sciences," 17th Ed., Mack Publishing Co., Easton, PA, p. 1280, 1985.

6. Several comments contended that certain OTC cough-cold drug products should be sold only in pharmacies and that general marketing of these products in places such as grocery stores, newspaper stands, and train stations should not be permitted. Some of the comments recommended that certain OTC drug products be dispensed by pharmacists and designated in a third class, separate from OTC or prescription, to be called "Pharmacy OTC Only." These comments maintained that the public should have the expert advice of pharmacists to make effective choices of OTC drug products.

One comment opposed a "pharmacy only" restriction and referred to the agency's conclusion on this "druggist monopoly concept" that was published in the **Federal Register** of June 4, 1974; 39 FR 19880–19881. This comment agreed with the position stated by the Department of Justice that the restriction of OTC drug product sales to pharmacies would have severe anticompetitive effects and inhibit the efficient distribution of OTC drug products to the consumer.

The issue of "a third class of drugs" (drugs that are available only in a pharmacy) has been considered previously in the OTC drug review, and the agency stated its position on this matter at that time. (See the **Federal Register** of June 4, 1974; 39 FR 19880.) The agency noted that although the Federal Food, Drug, and Cosmetic Act (the act) "permits imposition of whatever limitations or restrictions are necessary to assure the safe use of any drug, including restrictions on the channels of distribution, no controlled studies or other adequate research data have been supplied to support the position that any class of OTC drugs must be dispensed only by pharmacists in order to assure their safe use." Additionally, "restricting the sale of some or all OTC drugs only to pharmacies would decrease the number of outlets where the consumer could purchase OTC products, limit competition, and raise some OTC drug prices, with no attendant public benefit." The agency concluded that "it would be inappropriate to restrict the sale of OTC drugs to pharmacies based on anything less than proof that a significant safety issue was involved" (39 FR 19881) and that, because there was no public health concern at that time to justify the creation of a third class of drugs, the issue was solely an economic one.

More recently, the agency addressed the issue of a third class of drugs in response to two citizen's petitions that requested FDA to issue regulations to establish sale-by-pharmacist only of certain OTC drug ingredients. The agency denied the petitions, stating that a class of drugs for sale-by-pharmacist only is unnecessary because a public health need for such a limitation has not been demonstrated. OTC drug products must be adequately labeled for safe and effective use by laypersons, and if the agency were to find that the labeling for a particular drug product did not provide sufficient information for a layperson to use that product safely, it would take appropriate action. Further, the agency stated that the legal authority to create a sale-by-pharmacist class of drugs is questionable because under the act, there is no provision for an intermediate class of drugs between OTC and prescription products. The statutory requirement that a drug either be limited to prescription dispensing or available OTC with adequate directions for use seems to preclude the agency from establishing a class of drugs whose labeling would need to be supplemented by a pharmacist's instructions (Refs. 1 and 2).

The comments did not provide any controlled studies or other data adequate to demonstrate that a safety issue exists with respect to marketing OTC drug products in general, and certain OTC cough-cold drug products in particular, in places other than pharmacies. The agency is not aware of any such data, and therefore its position on a "third class of drugs," as stated above, is unchanged.

References

(1) Letter from F.E. Young, FDA, to D.C. Huffman, American College of Apothecaries, in OTC Volume 04GTFM, Docket No. 76N–052G, Dockets Management Branch.

(2) Letter from F.E. Young, FDA, to C.M. West, The National Association of Retail Druggists, in OTC Volume 04GTFM, Docket No. 76N–052G, Dockets Management Branch.

7. A number of comments objected to the continued marketing of many OTC cough-cold drug products which have not been proven safe and effective. These comments referred to 58 cough-cold active ingredients placed in Category III by the Panel. One comment stated that cough-cold drug products containing such ingredients are legally required to be either generally recognized as safe and effective or the subject of a new drug application and concluded that drugs which do not meet these criteria are not marketable; i.e., they are illegal.

FDA has stated that it is agency policy to take regulatory action prior to a final monograph against products that present a potential health hazard or a significant and substantial question of effectiveness (45 FR 31425 and 46 FR 47737). At this time, the agency is not aware of any information to show that any of the ingredients in question fits either of these criteria. Therefore, the agency will continue to review these ingredients under the standard OTC drug review process. The Panel's "placement" of ingredients in Category III represents only the Panel's recommendations to the agency regarding their safety and effectiveness. The agency's determination whether the ingredients are generally recognized as safe and effective, and not misbranded, will not be completed until the agency has finished its review and a final monograph has been issued. Until then, Category III ingredients may continue to be marketed. As originally promulgated, the OTC drug review procedural regulations permitted continued marketing of Category III ingredients after a final monograph became effective. However, FDA has revised the OTC drug review regulations so that an ingredient that is not included in the appropriate final monograph (nonmonograph condition) will be subject to regulatory action if marketed once that final monograph becomes effective. (See the **Federal Register** of September 29, 1981; 46 FR 47730.)

8. One comment stated that the Panel used an inappropriate standard in categorizing some Category II claims and placed claims such as "used by," "most recommended by doctors," and "improved" in Category II because they are difficult to substantiate. The comment contended that a claim is not false or misleading because it is difficult to substantiate, and that if it is factual, a claim should be permitted regardless of whether it can be demonstrated in controlled studies. The comment questioned whether the Panel was saying that a product cannot be

improved, adding that one would expect that a number of products would be "improved" as a result of the OTC drug review.

The OTC drug review program establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. Two principal conditions examined during the review are allowable ingredients and allowable labeling. The FDA has determined that it is not practical—in terms of time, resources, and other considerations—to set standards for all labeling found in OTC drug products. Accordingly, OTC drug monographs regulate only labeling related in a significant way to the safe and effective use of covered products by lay persons. OTC drug monographs establish allowable labeling for the following items: product statement of identity; names of active ingredients; indications for use; directions for use; warnings against unsafe use, side effects, and adverse reactions; and claims concerning mechanism of drug action.

The agency believes terms such as "used by" and "most recommended by doctors" are unrelated to the characteristics of the drugs in question and, therefore, do not relate in a significant way to the drugs' safe and effective use. Accordingly, the terms "used by" and "most recommended by doctors" are outside the scope of the OTC drug review. The agency emphasizes that even though terms such as "most recommended by doctors" are outside the scope of the OTC drug review, they are subject to the prohibitions in section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading. Such terms will be evaluated by the agency in conjunction with normal enforcement activities relating to that section of the act. Moreover, any term that is outside the scope of the review, even though it is truthful and not misleading, may not appear in any portion of the labeling required by the monograph and may not detract from such required information. (See comment 23 below.)

A number of cough-cold drug products will be "improved" as a result of the OTC drug review. Such improvements may include replacement of a Category III ingredient with a Category I ingredient, a change in the dosage of an ingredient to provide a safe and effective product, and new indications, warnings, or directions for use that are clearer to the consumer and protect against misuse.

In May 1977, The Proprietary Association (the trade association of manufacturers of nonprescription drugs) initiated a "Flag the Label" program, partially as a result of the OTC drug review, to alert consumers to significant changes in the ingredients or labeling of an OTC drug product (Ref. 1). This "Flag the Label" program informs consumers of changes in indications, dosages, active ingredients, directions, warnings, contraindications, or any other significant new information by using an attention-getting visual device (a flag) on the label. The agency endorses this program because it directs consumers' attention to important new product information, much of which results from the OTC drug review, without using words such as "improved," which could mislead consumers into thinking that the product is therapeutically superior to other comparable products.

Reference

(1) "Flag the Label Guidelines," The Proprietary Association, Washington, DC, in OTC Volume 04GTFM.

9. One comment requested that the following description of coryzal rhinitis be added to the Panel's discussion of rhinitis under the heading *Diseases and Related Symptoms Relieved by OTC Cold, Cough, Bronchodilator and Antiasthmatic Products* at 41 FR 38321: "Coryzal rhinitis results in the symptoms of sneezing, rhinorrhea, and nasal congestion due to edema of the nasal mucosa. The discharge is serous at first and may subsequently become mucoid or mucopurulent. The feeling of nasal congestion may intensify from suppression of the sense of smell."

The agency has reviewed the Panel's discussions of the common cold and the reduction of nasal secretions and believes that the symptoms of coryzal rhinitis as described by the comment and the symptoms of the common cold as described by the Panel are similar. The Panel concluded that the effectiveness of OTC antihistamine cough-cold products in relieving the symptoms of the common cold had not been demonstrated (41 FR 38380). However, based on new data submitted in response to the Panel's report, the agency has proposed a Category I indication for antihistamine drug products for the relief of the symptoms of sneezing and runny nose associated with the common cold. (See the tentative final monograph for OTC antihistamine drug products at 50 FR 2203.) Based on this proposed Category I indication, the agency does not see the need to expand the Panel's discussion of rhinitis, as requested by the comment.

B. General Comments on the Switch of Prescription Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drugs to OTC Status

10. Several comments disagreed with the agency's dissent from the Panel's recommendations to switch several ingredients from prescription to OTC marketing status, arguing that this dissent was based on comparative safety and effectiveness. The comments contended that the agency used criteria that were not mandated by statute or the OTC drug review in determining whether these drugs could be switched to OTC status. The comments concluded that the statutory criterion for prescription status is whether the drug may be safely used without the supervision of a licensed practitioner, and the fact that there are more effective drugs available OTC or even that there are less toxic drugs already available OTC is irrelevant to the determination required by the statute.

The agency agrees that it is not within the scope of the OTC drug review regulations to use comparative safety and comparative effectiveness as criteria for switching a drug from prescription to OTC status. In dissenting from or accepting the recommendations of advisory review panels to switch ingredients from prescription to OTC marketing status, the agency has judged these ingredients individually on whether they can be generally recognized as safe and effective for OTC use. General recognition of safety and effectiveness is not based on comparison.

In 1976, while considering the Panel's recommendations to switch certain prescription drugs to OTC marketing status, the agency considered the safety of these drugs for OTC use and did not believe at that time that they were safe for switching. For example, the agency concluded that the marketing status of diphenhydramine hydrochloride as an antitussive should be resolved by first considering the approvability of the pending supplemental NDA for OTC use of a cough syrup product containing this ingredient (41 FR 38313). The agency also concluded at that time that diphenhydramine hydrochloride as an antihistamine should remain a prescription drug because of its pronounced tendency to produce sedation in a high proportion of those persons using it. The agency pointed out that no diphenhydramine hydrochloride product was being marketed OTC as an antihistamine at any dosage level. Subsequently, the agency determined that the risk of drowsiness presented by

diphenhydramine hydrochloride did not provide sufficient reason to restrict this ingredient to prescription status so long as adequate warnings concerning drowsiness are included in the labeling of the product. (See the tentative final monograph for OTC antihistamine drug products, 50 FR 2206; and the amendment to the tentative final monograph for OTC antihistamine drug products, 52 FR 31913.)

The other ingredients the Panel recommended switching from prescription to OTC drug use have also been judged by the agency in accordance with the standards set forth in the act and the OTC drug review regulations in § 330.10(a)(4). For example, the agency has proposed that promethazine hydrochloride, as a single ingredient, be classified in Category III in the tentative final monograph for OTC antihistamine drug products because of the lack of safety data on long-term use, not because of comparison with other OTC drug ingredients (50 FR 2202). (See also the discussion of promethazine combinations in "Summary of the Agency's Changes in the Panel's Recommendations," in Part II. paragraph B. below.) Thus, the agency is applying the statutory criterion referred to by the comment.

11. One comment objected to FDA's allowing the OTC marketing, immediately following publication of the advance notice of proposed rulemaking, of the ingredients that the Panel recommended be switched from prescription to OTC status. The comment stated that no opportunity was permitted for public objections to this change in marketing status. Further, the comment stated that allowing the immediate OTC sale of these ingredients causes confusion and a dilemma in the drug distribution system because if these ingredients are now considered OTC items by FDA, then all such drug products currently in distribution containing these ingredients and bearing the prescription legend are misbranded and in violation of federal law.

The proposed policy for interim OTC marketing of ingredients previously limited to prescription use immediately following the publication of a panel's report and proposed monograph was published in the **Federal Register** of December 4, 1975 (40 FR 56675), and public comment was invited. Subsequently, a final policy statement regarding the marketing status of prescription ingredients recommended for OTC use was published in the **Federal Register** of August 4, 1976 (41 FR 32580). Briefly, the policy set forth in § 330.13 provides that an OTC drug product containing an active ingredient limited to prescription use on May 11, 1972, or an active ingredient at a dosage level higher than that available in an OTC drug on December 4, 1975, may be marketed OTC after the date of publication of an advance notice of rulemaking proposed in the **Federal Register**, if the Panel has classified the ingredient in Category I and the Commissioner has not dissented. Such marketing is subject to the risk that the Commissioner may not accept the Panel's recommendations and may instead adopt another position that may require relabeling, recall, or other regulatory action.

The agency does not agree with the comment that interested persons did not have ample opportunity to express their points of view prior to the Panel's recommendations affecting the prescription status of cough-cold drug products. During the 3½ years of the Cough-Cold Panel's deliberations, each Panel meeting was announced in the **Federal Register** and, at each session, an opportunity was afforded to any interested person to present his or her views relevant to the Panel's work. Those portions of the Panel's deliberations not open to the public were attended by a consumer and an industry liaison, and summary minutes of each Panel session were put on public display in the Dockets Management Branch (address above). Furthermore, an information copy of the Panel's report was made available to the public prior to publication in the **Federal Register**.

It may happen, as the comment points out, that during the pendency of the rulemaking some manufacturers may choose to market previously prescription ingredients OTC, while others choose to continue marketing the same ingredients with the prescription legend. As noted, these ingredients are marketed OTC subject to the risk that the agency may not accept the Panel's recommendation and may instead adopt a different position at any time prior to the effective date of a final monograph at which time products containing any of these ingredients may be subject to relabeling, recall, or other regulatory action. FDA does not believe that this interim marketing enforcement policy, which affords manufacturers some choice while the rulemaking is ongoing, has been unduly disruptive of the marketplace.

12. One comment requested that the agency permit the continued sale of drugs switched from prescription to OTC status as prescription drugs for a specified period of time.

As discussed in comment 11 above, when an advisory review panel recommends that a prescription ingredient be included in an OTC drug monograph for the same indication, OTC marketing under the terms of 21 CFR 330.13 may occur. However, during the pendency of the rulemaking, manufacturers may choose instead to continue prescription marketing of the ingredient in light of the possibility that the agency may ultimately decide that OTC marketing is not appropriate. However, after the effective date of the final OTC drug monograph (usually 12 months after its publication in the **Federal Register**), if the ingredient and indication are included in the monograph, a drug product containing the ingredient as switched to OTC status may not be marketed as a prescription product. The agency believes that manufacturers will have ample opportunity to prepare for the change in marketing status from prescription to OTC marketing.

13. Several comments were opposed to the OTC sale of certain antihistamine, nasal decongestant, and bronchodilator drugs (which were previously available only by prescription) unless these drugs are packaged in child-resistant containers. One of the comments stated that prescription drugs are subject to the requirements of the safety packaging law and are required to be dispensed in safety packaging. However, once prescription drugs are allowed to be sold OTC, they are not required to be dispensed in safety packaging. The comments stated that children will be exposed to potential poisoning from these drugs without the safety packaging requirements. The comments urged that FDA not allow these drugs to be sold OTC unless they are packaged in child-resistant containers.

FDA agrees that these and all OTC drugs should be safe for consumer use. However, statutory authority to require child-resistant closures rests with the Consumer Product Safety Commission (CPSC) under the Poison Prevention Packaging Act of 1970. That act provides that hazardous or potentially hazardous products must be sold in safety packaging that most children under 5 years of age cannot open. FDA's Division of Epidemiology and Surveillance in the Center for Drugs and Biologics compiles poison control case reports and statistics and forwards them to CPSC for review. If the poison control data indicate that a particular drug or class of drugs presents a poisoning hazard to children due to its packaging,

CPSC may determine if child-resistant closures should be required. Additionally, consumers may petition the CPSC to study hazardous drugs that could be toxic to young children and to determine whether child-resistant closures are warranted.

FDA is aware that CPSC has reviewed the available data on antihistamines to determine if child-resistant closures are warranted for OTC drug products containing these ingredients. CPSC published a final rule requiring that drug products containing more than 75 mg diphenhydramine hydrochloride in a single package and in a dosage form intended for oral administration have child-resistant packaging. (See CPSC Requirements for Child-Resistant Packaging; Diphenhydramine Hydrochloride, published in the **Federal Register** on February 15, 1984; 49 FR 5737.) CPSC found that serious toxic effects can be produced with doses of diphenhydramine hydrochloride as low as 100 mg. In the **Federal Register** of August 15, 1984 (49 FR 32565), CPSC amended the regulation to broaden its scope by requiring child-resistant packaging for preparations containing more than 66 mg diphenhydramine base in any oral dosage form. Although CPSC reviewed the toxicity of other antihistamines, it did not propose that any antihistamine other than diphenhydramine be required to be packaged with child-resistant closures. Because of the lack of significant toxicity data for antihistamines other than diphenhydramine, CPSC concluded that child-resistant closures were not necessary for these drugs, regardless of the amount of drug contained in each package. At this time, CPSC is not reviewing the other drug products mentioned by the comments.

FDA urges that manufacturers voluntarily place child-resistant closures on any OTC drug product that could be toxic to young children.

C. General Comments on Miscellaneous OTC Ingredients

14. One comment suggested that an upper limit of menthol as a flavoring agent in syrups, lozenges, sprays, etc., is needed to clearly distinguish between menthol used as an active ingredient and menthol used as an inactive ingredient.

Menthol is generally recognized as safe for use as a flavoring substance in foods. (See 21 CFR 172.515 and 182.20.) Section 172.515 specifies that such flavoring substances be "used in the minimum quantity required to produce their intended effect and otherwise in accordance with all the principles of good manufacturing practice." These regulations do not specify an upper concentration for menthol used as a flavoring agent, and the agency is not proposing such a limit for OTC drug products at this time. However, the agency invites information and comments on: (1) The minimum concentration of menthol needed to achieve a flavoring effect and (2) the minimum concentration of menthol needed to achieve a therapeutic effect. The agency will consider such information in determining how to distinguish between menthol as an active ingredient and menthol as an inactive ingredient and whether to establish minimum levels. In any case, if menthol is present at a therapeutic level in a product, the agency would consider it to be an active ingredient in that product.

15. One comment requested that topical analgesics be included in item 8 of the Panel's table at 41 FR 38320, which listed symptoms and the corresponding pharmacologic groups of drugs for the treatment of these symptoms. The comment suggested that item 8, "Generalized aching," be expanded to include the Category I labeling indications for topical analgesics, counterirritants, and rubefacients recommended by the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (the Topical Analgesic Panel).

The agency discussed this use of topical analgesics in the notice of proposed rulemaking for OTC external analgesic drug products published in the **Federal Register** of February 8, 1983 (comment 18 at 48 FR 5859).

16. One comment expressed concern about the synergistic effect that occurs when alcohol is combined with ingredients of cough-cold products, such as antihistamines, and that the Panel's report ignored the use of alcohol in marketed cough-cold products that contain antihistamines.

The synergism between alcohol and antihistamine that heightens the drowsiness side effect of most antihistamines has been reported in the literature (Refs. 1 and 2). However, because alcohol is an excellent solvent and stabilizer and may provide palatability to distasteful ingredients, it is used in OTC antihistamine-containing cough-cold products as a pharmaceutical necessity (Ref. 3). The agency finds that the concentrations of alcohol commonly used in antihistamine-containing cough-cold products are sufficiently low that the quantity of alcohol consumed with a single dose of antihistamine does not constitute a hazard (Ref. 4). The agency finds that the benefits of using alcohol in this manner outweigh the minimal risk presented.

The Panel recognized the synergistic effects of the interaction between alcohol and antihistamines and in its recommended warning in § 341.72(b)(4) cautioned adult consumers not to drink alcoholic beverages while taking antihistamines. The agency also recognizes that alcohol potentiates central nervous system depressants and interacts with certain drugs. The agency shares the Panel's concern regarding additional central nervous system effects, such as drowsiness, that can occur if alcoholic beverages are used simultaneously with antihistamine drug products (Ref. 5). However, drowsiness itself is not a sufficient reason to prohibit the OTC use of such products when the labeling provides appropriate warnings and essential information. In the tentative final monograph for OTC antihistamine drug products (50 FR 2209), the agency proposed a stronger warning than the one recommended by the Panel—"May cause marked drowsiness; alcohol may increase the drowsiness effect. Avoid alcoholic beverages while taking this product * * *." (See § 341.72(c)(4) at 50 FR 2216.)

The Panel also recommended in § 341.50(c) that products containing concentrations of alcohol greater than 10 percent (weight/weight) not be given to children under 6 years of age except under the supervision of a doctor. Alcohol depresses the central nervous system over a wide range of doses. Threshold effects are observed at blood levels of 20 to 50 milligrams (mg) per 100 milliliters (mL), and a detectable impairment of vision occurs at a blood level of about 15 mg per 100 mL (Ref. 6). In its report of March 1982, the American Academy of Pediatrics (AAP) recommended limiting the amount of alcohol in a container of an OTC drug product labeled for use in children to an amount that, if entirely consumed accidentally by a 2-year-old child as a single dose or accumulated over a period of time, would not produce a blood ethanol concentration level in excess of 25 mg per 100 mL of blood (Ref. 4). The AAP also recommended that drug products be required to have safety closures if they contain alcohol in concentrations greater than 5 percent (volume/volume).

The AAP's report was published in March 1984 (Ref. 7). In the published report, the AAP reiterated the concerns expressed in its 1982 report and stated that it is desirable that no ethanol be

included in medicinal products intended for use in children. However, if ethanol is required to solubilize the active ingredients the following recommendations should be met: (1) OTC liquid preparations should be limited to a maximum of 5 percent (volume/volume) ethanol, (2) physician supervision is suggested for children less than 6 years using OTC preparations containing alcohol, (3) the amount of ethanol contained in any medicinal preparation should not be able to produce a blood concentration greater than 25 mg per 100 mL after a single recommended dose, (4) appropriate intervals between doses should be prescribed to prevent the accumulation of blood alcohol, (5) the packaged volume of ethanol-containing products should be kept to a reasonable minimum to prevent potential lethal ingestions, and (6) safety closures should be recommended for medications with greater than a 5 percent ethanol content (Ref. 7).

FDA's position regarding safety closures has been discussed in comment 13 above. The agency is considering the adoption of the recommendations made by the AAP regarding limitations in the alcohol content of drug products labeled for use by children and invites specific comment on these recommendations. Pending a final decision, the Panel's recommendation to limit the alcohol content to less than 10 percent in cough-cold drug products labeled for use in children under 6 years of age is not being included in this tentative final monograph. The agency urges manufacturers to use the least possible amount of alcohol to achieve solubility, stability, and palatability for all cough-cold drug products.

References

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(3) Gennaro, A.R., editor, "Remington's Pharmaceutical Sciences," 17th Ed., Mack Publishing Co., Easton, PA, p. 219, 1985.

(4) "Ethanol in Over-the-Counter Drugs for Children," Report to the Food and Drug Administration, Bureau of Drugs, by the Committee on Drugs, American Academy of Pediatrics, March 1982.

(5) Food and Drug Administration, "Alcohol-Drug Interactions," *FDA Drug Bulletin*, Vol. 6, p. 11, Nov. 5, 1979.

(6) Maling, H.M., "Toxicology of Single Doses of Ethyl Alcohol," *in* "International Encyclopedia of Pharmacology and Therapeutics," Pergamon Press, Elmsford, NY 2:277–299, 1970.

(7) Committee on Drugs, American Academy of Pediatrics, "Ethanol in Liquid Preparations Intended for Children," *Pediatrics*, 73:405–407, 1984.

17. One comment objected to the Panel's Category III classification of ascorbic acid (vitamin C), considering that the Panel recommended the switch of more potent drugs from prescription to OTC marketing status. Another comment objected to reports that state there is no scientific justification for the claim that vitamin C is beneficial in preventing the common cold. This comment personally attested to the benefits of vitamin C in preventing the common cold or alleviating its uncomfortable effects, particularly runny nose. The comment added that this vitamin is also beneficial if taken in the "very beginning" stages of a sore throat.

The Panel placed vitamin C in Category III after reviewing a number of studies and concluding that "the published data support a beneficial effect of ascorbic acid on the severity and perhaps frequency of the 'common cold' when given in dosages exceeding the daily requirement," but that "it is not yet clear that this effect is clinically significant." The Panel also stated that "the magnitude of the dosages needed and the optimum schedule for prophylaxis and therapy remain to be determined" (41 FR 38417).

The Advisory Review Panel on OTC Vitamin, Mineral, and Hematinic Drug Products also reviewed vitamin C and stated that the OTC drug use of vitamin C for its protective or therapeutic effect on the course of the common cold is presently not supported by adequate controlled clinical studies. Although claims have been made for the beneficial effects of 500 to 1,000 mg or more of vitamin C daily for the treatment and/or prevention of the common cold, double-blind studies have not adequately demonstrated this effect and are required to evaluate fully the validity of the claim (44 FR 16142).

The Cough-Cold Panel's recommendations to switch several drugs from prescription to OTC status were based on the available safety and effectiveness data, and dosage information. Similar data and information were not available regarding the use of vitamin C to prevent and/or treat the common cold.

In order for vitamin C to be classified as Category I for prevention and/or treatment of the common cold, there must be data demonstrating the ingredient to be safe and effective for these uses. Such data for vitamin C have not yet been submitted, nor did the comment provide such data. Accordingly, vitamin C remains in Category III in this tentative final monograph.

D. General Comments on Dosages for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drugs

18. One comment stated that the Panel's recommended dosage statements are inconsistent with regard to equivalent dosages for different salts of a drug. The comment explained that the dosage for phenylpropanolamine preparations in § 341.20(e) of the Panel's recommended monograph is based on the phenylpropanolamine hydrochloride equivalent; however, the Panel did not differentiate the active moiety content of the salts of other drugs such as codeine, dextromethorphan, and ephedrine. The comment recommended that the agency adopt the format used for phenylpropanolamine, selecting a particular salt as the representative form of that drug and identifying the dosage for that salt with a statement similar to that used for phenylpropanolamine. The comment suggested that the sulfates be used as the representative forms for codeine and ephedrine, and that the hydrobromide salt be the representative form for dextromethorphan.

The Panel recommended that the dosage for phenylpropanolamine preparations be "based on the phenylpropanolamine hydrochloride equivalent" because data were submitted to the Panel to support this dosage (Refs. 1 and 2). In its report, when dosages for drugs were not based on representative forms, the Panel determined that the same doses for various salts of these drugs were generally equivalent based on historical usage and the Panel's experience with the various drugs. Moreover, this approach using the same dose for codeine sulfate and phosphate, and ephedrine hydrochloride and sulfate is consistent with standards established in USP XXI (Ref. 3). At this time, the agency is not aware of any data showing that the dosages recommended by the Panel for codeine and ephedrine and their salts should be stated differently, and the comment did not submit any data demonstrating the need for establishing particular salts of these drugs as representative drug forms. With regard to dextromethorphan and dextromethorphan hydrobromide, the agency has determined that the dosage should be equivalent to dextromethorphan hydrobromide. (See the final monograph for OTC antitussive drug products published in the **Federal**

Register of August 12, 1987; 52 FR 30042.) The agency will consider identifying representative forms of drugs on a case-by-case basis if data are submitted showing that a change is necessary.

References

(1) OTC Volume 040273.
(2) OTC Volume 040285.
(3) "The United States Pharmacopeia XXI—National Formulary XVI," United States Pharmacopeial Convention, Rockville, MD, pp. 243–244, and 372, 1985.

E. General Comments on Labeling and Advertising for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drugs

19. One comment stated that OTC drugs should be proven safe and effective, and have true, clear, understandable, and more detailed labeling.

The agency agrees with the comment. Upon completion of the OTC drug review, OTC drug monograph standards of safety, effectiveness, and labeling will be developed for all OTC active ingredients, assuring safe and effective OTC drug products. Moreover, the agency has given serious consideration to the importance of accurate labeling and the consumer's comprehension of the intended message in the labeling. The expertise of the various panels was directed toward assuring informative, medically accurate OTC labeling. The agency, on its own initiative and in response to public comments, is modifying labeling proposed by the panels, where necessary, to make it clearer and more understandable to consumers.

20. Five comments objected to the Panel's recommendation that all inactive ingredients be listed in the labeling of OTC cough-cold drug products. The comments argued that a list of inactive ingredients in the labeling would be meaningless, confusing, and misleading to most consumers. The comments noted that the Federal Food, Drug, and Cosmetic Act does not require that the inactive ingredients of drug products be included on a label and argued that listing these ingredients would crowd out information that is more meaningful to consumers. Two comments agreed with the Panel's recommendation.

The Federal Food, Drug, and Cosmetic Act specifies the requirements for ingredient labeling of OTC drug products. Section 502(e) of the act (21 U.S.C. 352(e)) requires that all active ingredients and certain other ingredients, whether included as active or inactive, be disclosed in the labeling. The act also limits the requirement for stating quantity of ingredients in OTC drug products to those specifically mentioned in section 502(e). Although the act does not require the disclosure of all inactive ingredients in the labeling of OTC drug products, the agency agrees with the Panel that listing of inactive ingredients in OTC drug product labeling would be useful information for some consumers. Consumers with known allergies or intolerances to certain ingredients would then be able to identify substances that they may wish to avoid.

The Proprietary Association, the trade association that represents approximately 85 OTC drug manufacturers who reportedly market between 90 and 95 percent of the volume of all OTC drug products sold in the United States, has established guidelines (Ref. 1) for its member companies to list voluntarily inactive ingredients in the labeling of OTC drug products. Under another voluntary program begun in 1974, the member companies of The Proprietary Association have been including the quantities of active ingredients on OTC drug labels. The agency is not at this time proposing to require the listing of inactive ingredients in OTC drug product labeling. However, the agency commends these voluntary efforts and urges all other OTC drug manufacturers to similarly label their products.

Reference

(1) "Guidelines for Disclosure of Inactive Ingredients in OTC Medicines," The Proprietary Association, Washington, DC, July 12, 1984, in OTC Volume 04GTFM.

21. One comment agreed with the Commissioner's statement in the preamble to the advance notice of proposed rulemaking that manufacturers should include information concerning changes in dosages and reformulation in the labeling of drug products (41 FR 38313), but objected to placing this information on the principal display panel of the label. The comment also requested a time limit on how long a manufacturer would be required to continue providing such information in the labeling, stating that 1 year after reformulation of the product would be an appropriate limit.

Currently, there are no regulations requiring the inclusion of information concerning changes in dosages and reformulation in the labeling of OTC drug products, and the agency is not proposing any at this time. However, The Proprietary Association has instituted a program in which manufacturers of OTC drug products are encouraged to inform consumers voluntarily in the labeling of changes in dosages and formulations. (See comment 8 above.) The agency commends the program and encourages its continuation.

22. Several comments were opposed to the number and type of warnings proposed by the Panel for OTC cough-cold products. One comment stated that terms such as "monoamine oxidase inhibitor," "enlargement of the prostate gland," "glaucoma," "antihypertensive," and "antidepressant" are meaningless to all but a limited number of consumers. The comment further stated that it is redundant to use such terms in addition to "except under the advice and supervision of a physician" when the consumer has already been diagnosed by a physician as having these conditions. Several comments stated that warnings which contain specific contraindications should be based on sound epidemiological data, and that the addition of extensive warnings tends to reduce the impact of the important labeling statements. The comments recommended that FDA accept only those warnings which are necessary and important, and which are applicable to a significant portion of the target population.

The agency agrees that too many warning statements reduce the impact of important statements. The agency also believes that the warnings it has proposed provide important information to consumers. As each segment of the monograph for cough-cold drug products was proposed, many of the Panel's recommended warnings were revised, simplified, combined, or eliminated. For example, the phrase "except under the advice and supervision of a physician" has been shortened to "unless directed by a doctor." Some information recommended by the Panel in *"Warnings,"* such as age restrictions, is now included in the *"Directions"* section. Contraindications for specific populations, e.g., people with hypertension or glaucoma, have been included only when there is evidence to support these contraindications.

With regard to the terms in the Panel's warnings which the comment believed would be meaningless to consumers, the agency stated in the tentative final monograph for OTC nasal decongestant drug products that terms such as "monoamine oxidase inhibitor," "antihypertensive," and "antidepressant" may be confusing to consumers and deleted "monoamine oxidase inhibitor," substituted "high blood pressure" for "antihypertensive," and substituted "depression" for "antidepressant" (50 FR 2231). Similar changes will be made in other monographs as appropriate. Because antihypertensive and antidepressant

drugs are widely prescribed, persons taking these medications should be alerted to drug interactions that can occur if they are taken simultaneously with some OTC drugs. Likewise, although consumers may have been diagnosed by a physician as having enlargement of the prostate gland or glaucoma, they may not be aware that a particular OTC drug product contains ingredients that they should not use.

The agency believes that, with the above changes, the proposed warning statements for OTC cough-cold products will provide important, understandable information to the consumer in a concise manner.

23. Two comments contended that FDA does not have the authority to legislate the exact wording of OTC labeling claims. The comments stated that limiting the indications to the exact terminology of the monograph is overly restrictive because the Panel itself had used alternate terminology throughout the report in discussing the indications for these products. One comment requested that more flexibility in labeling be permitted by adding to the approved indications a statement as follows: "* * *, or similar indications statements which are in keeping with the Panel's report."

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either: (1) The specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks in an applicable monograph or other regulation, e.g., 21 CFR 201.63 or 330.1(g).

In this tentative final monograph, supplemental language relating to indications has been proposed and captioned as *Other Allowable Statements*. Under FDA's revised labeling policy (51 FR 16258), such statements are included at the tentative final stage as examples of other truthful and nonmisleading language that would be allowed elsewhere in the labeling. In accordance with the revised labeling policy, such statements would not be included in a final monograph. However, the agency has decided that, because these additional terms have been reviewed by FDA, they should be incorporated, wherever possible, in final OTC drug monographs under the heading "Indications" as part of the indications developed under the monograph.

24. Two comments objected to limiting the terminology in the indication statements to "temporarily relieves" or "temporary relief of" when the actual duration of action is known in hours. These comments requested that a statement of a definite duration of action (e.g., "12 hours of relief") replace a term such as "temporary relief" in the labeling of drug products with a known duration of action.

Information on duration of action is provided by the dosage intervals given in the directions for use in the cough-cold monograph, e.g., 2 or 3 drops or sprays every 12 hours. The agency believes that it is unnecessary to repeat this information in the indications. A manufacturer may use a term such as "12 hours of relief" elsewhere in the labeling if the term is true and not misleading, but such terms are not being proposed in the tentative final monograph.

25. One comment, noting that the Panel restricted product identification to the terms defined in § 341.3 of its recommended monograph, requested that definitions of the terms "cold (common cold) product" and "sinus congestion product" be included in the monograph, so that these terms could be used to identify products. Other comments objected to the Panel's recommendation that product names or labeling claims that contain the words "cough" or "cold," such as "cough syrup," "common cold," "cold tablets," "cold capsules," "cold formula," and "cold medicine," not be allowed in OTC drug product labeling. These comments contended that such terms are truthful in the context of the total label and are meaningful to consumers. Several comments added that the Panel's recommendations conflict with existing trademark laws and arbitrarily prohibit the use of lawfully registered trademarks.

Although the Panel restricted product identifications to those terms defined in § 341.3 of its recommended monograph, the agency is including in each monograph a "statement of identity" paragraph that sets forth acceptable terms for product identification. As stated in § 201.61 (21 CFR 201.61), the statement of identity of an OTC drug is limited to the established name of the drug, if any, followed by an accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug. The established name of a drug, as defined in section 502(e)(3) of the act (21 U.S.C. 352(e)(3)) is: (1) The official name designated pursuant to section 508 of the act, (2) the official name recognized in an official compendium, if the drug has no designated official name, or (3) the common or usual name of the drug if neither (1) nor (2) apply. Terms employed to describe the general pharmacological category(ies) or principal intended action(s) of the drugs covered by this monograph are "antihistamine," "antitussive," "bronchodilator," "expectorant," and "nasal decongestant." An example of a statement of identity for an antihistamine drug product containing chlorpheniramine maleate to relieve hay fever would be "chlorpheniramine maleate" followed by the term "antihistamine," i.e., the established name of the drug and its pharmacological category. Wherever possible, the agency prefers to use the general pharmacologic category as the statement of identity because information on the principal intended action is provided in the indications. However, in instances where the pharmacologic category is not appropriate as the statement of identity, the principal intended action is used. For example, the statement of identity for an antihistamine used as a nighttime sleep-aid is "nighttime sleep-aid."

The agency believes that, while naming the symptom or condition for which the product is used, terms such as "cold tablets," "cold capsules," "cold formula," "cold medicine," "cold (common cold) product," "cough syrup," or "sinus congestion product" convey a general use but do not convey the drug's principal intended action as well as the terms "antihistamine," "nasal decongestant," etc. The agency does not oppose the inclusion of such terms in the names of products; however, these terms are not required and are not being included in the labeling in the

monograph. Product names, which may include terms such as "cold formula," are considered to be outside the scope of the OTC drug review, but are subject to the prohibitions in section 502 of the act relating to labeling that is false or misleading. Such terms, whether used in product names or in other parts of the labeling that are not covered by the monograph, will be evaluated by the agency in conjunction with normal enforcement activities relating to that section of the act.

In reviewing the terms defined by the Panel in recommended § 341.3, the agency concludes that "antihistamine" in paragraph (e) conveys the pharmacological category, but "allergy product" in paragraph (b) or "hay fever product" in paragraph (k), do not convey the pharmacological category or principal intended action of the product. Thus, the term "antihistamine" has been proposed as the statement of identity in the tentative final monograph for OTC antihistamine drug products (50 FR 2216), but "allergy product" and "hay fever product" have not been included. However, these terms are similar to the terms "cold tablets," "cold formula," "sinus congestion product," etc. in that they name the condition or symptom for which the product is used, and may be used in the names of products as discussed in the preceding paragraph.

26. One comment objected to the Panel's recommendation against the use of the words "works internally" and stated that these words clearly and directly tell the consumer the difference between products which have different routes of administration, such as products for external application or for intranasal use, as opposed to products for systemic absorption by an oral or rectal route.

The agency believes that the term "works internally" provides little useful information to the consumer and, in fact, can be misleading. When self-administering a medication, it is important for the consumer to know how to use the drug, the nature of any side effects that can occur, and any contraindications for its use. This information is contained in the label directions and warnings on the product. Further, the label warnings will inform the consumer of any systemic or internal effects which might occur from using the drug.

The term "works internally" does not provide specific information that facilitates safe and effective use of an OTC drug product or prevents misuse and might well serve to confuse consumers. Many topically applied products have systemic effects. The agency believes that it would be confusing to consumers to have label directions that state that the product is to be used topically, while elsewhere on the label it states that the product "works internally." Therefore, the agency agrees with the Panel that the term "works internally" should be classified in Category II.

27. One comment requested that advertising claims for the effectiveness of OTC drug products containing ingredients that are placed in Category III for lack of data to show effectiveness not be allowed during the testing period of these ingredients. The comment recognized that this request may come under the jurisdiction of the Federal Trade Commission (FTC).

As discussed below, the FTC has the primary responsibility for regulating OTC drug advertising. FDA has forwarded copies of the comments concerning cough-cold advertising to the FTC for its consideration. Manufacturers are responsible for adhering to applicable statutory and regulatory standards with respect to advertising claims regardless of whether there is ongoing testing. FDA notes that, since the comment was submitted, the regulations concerning OTC drug review procedures have been revised to delete the provision that had allowed continued marketing of an OTC drug product with a condition classified in Category III after publication of a final monograph pending further testing (see 46 FR 47730; September 29, 1981). (See comment 28 below.)

28. Several comments asserted that the Panel went beyond its charter by making statements concerning the advertising of the products under its review. The comments stated that FDA did not grant such authority in the procedures established for OTC panels. The comments further argued that the Panel's statements on OTC drug advertising were not only inappropriate for inclusion in the report, but were also based on inadequate information because, according to FDA procedures, data and information pertaining to advertising were not submitted to the Panel.

The OTC drug review procedures do not preclude a panel from expressing its concern about OTC drug advertising. The Panel's statements and recommendations on OTC drug advertising (41 FR 38334) were partly based on a presentation made to the Panel by a representative of the Council on Children, Media and Merchandising in April 1975. The presentation included a film and documentation on the use of the package and labeling of OTC drugs in advertising and the possible effect of advertising on children (Ref. 1). FTC has the primary responsibility for regulating OTC drug advertising, and FDA has forwarded copies of the comments concerning cough-cold advertising to the FTC for its consideration (Ref. 2). FDA does, however, have the authority to regulate OTC drug advertising that constitutes labeling under the Federal Food, Drug, and Cosmetic Act. See, e.g., *United States* v. *Article of Drug * * * B-Complex Cholinos Capsules*, 362 F.2d 923 (3d Cir. 1966); *V.E. Irons, Inc.* v. *United States*, 244 F.2d 34 (10th Cir.), *cert. denied*, 354 U.S. 923 (1957). In addition, for an OTC drug to be generally recognized as safe and effective and not misbranded, the advertising for the drug must satisfy the FDA regulations at § 330.1(d) (21 CFR 330.1(d)), which state that the advertising may prescribe, recommend, or suggest the drug's use only under the conditions stated in the labeling. If advertising for an OTC cough-cold drug product offers the product for conditions not included in the final monograph labeling, the drug product may be subject to regulatory action by FDA.

References

(1) Summary Minutes of the 18th Meeting of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products, April 3, 4, and 5, 1975, Dockets Management Branch.

(2) Letter from S. Bader, FDA, to W. Snyder, FTC, May 6, 1982, in OTC Volume 04GTFM, Docket No. 76N-052G, Dockets Management Branch.

F. General Comments on Testing Guidelines

29. Several comments expressed concerns about the testing guidelines recommended by the Panel for Category III OTC single drug ingredients and combinations. The comments urged the Commissioner not to shorten the period of time within which studies must be completed as recommended by the Panel (41 FR 38312) but instead to expand the period of time where good cause can be shown. Other comments stated that the clinical testing time allotted for drugs in Category III is "excellent" or entirely appropriate because of a lack of specific proven methods for some of the studies being recommended. Some comments expressed concern about the competition for a limited number of investigational facilities and trained research personnel which could result from testing of each type of Category III ingredient and combination.

The agency has not addressed specific testing procedures in this document. In revising the OTC drug review procedures relating to Category III,

published in the **Federal Register** of September 29, 1981 (46 FR 47730), the agency advised that tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. Instead, the agency will meet with industry representatives at their request to discuss testing protocols. The revised procedures also state the time in which test data must be submitted for consideration in developing the final monograph. (See also part II. paragraph A.2. below—*Testing of Category II and Category III conditions.*)

30. Referring to the testing of Category III drugs for effectiveness, one comment stated that government agencies should perform absolutely essential testing on prototype drug products and provide industry with the results. According to the comment, the cost of testing could be prorated to the companies marketing the drugs. The comment objected to the testing of OTC drug products by industry because of duplication of studies of the same drug by many companies and because of the moral, ethical, and economic issues involved in utilizing human subjects in testing Category III drugs for effectiveness.

In the preamble to the final rule revising the procedures relating to Category III conditions, the agency stated that "it is the responsibility of the manufacturer of a drug to have adequate tests that meet the statutory requirements before marketing the drug." (See the **Federal Register** of September 29, 1981; 46 FR 47732.) In this document, the agency also stated that "FDA will require adequate and well-controlled studies except where the agency waives this requirement as unnecessary or inappropriate. The agency advises that § 330.10(a)(4)(ii) does permit reports of significant human experience during marketing to be used as corroborative support for general recognition of effectiveness" (46 FR 47731).

Regarding other considerations mentioned by the comment in connection with Category III testing, as discussed in comment 29 above, the agency emphasizes its intention to meet with manufacturers at their request to discuss protocols and other testing issues involving conditions that industry is interested in upgrading. In many instances, reformulation of products to replace Category III ingredients with Category I ingredients will also eliminate a large portion of the costs of testing products containing Category III drugs.

31. Two comments requested modification of the Panel's recommended guidelines for the evaluation and standardization of cough-cold timed-release formulations (41 FR 38331).

These guidelines were published as the Panel's recommendations, but the agency is not adopting them or commenting on them at present. In the **Federal Register** of October 28, 1977 (42 FR 56756), the agency stated that dosage recommendations in the Panel's monograph apply only to conventional formulations. Timed-release formulations are considered new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)). Timed-release formulations are complex such that the state of the art does not permit adequate standardization of them for inclusion in an OTC drug monograph (42 FR 56756). In order to market a timed-release formulation, an approved NDA containing appropriate bioavailability data is required under section 505 of the act (21 U.S.C. 355) and FDA regulations in 21 CFR Part 314. Persons interested in testing or marketing such products should consult with the Office of Drug Research and Review (formerly the Office of New Drug Evaluation), Center for Drug Evaluation and Research.

G. General Comments on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Combination Drug Products

32. One comment contended that the Panel endorsed combination products which did not meet the "normal FDA standards." The comment pointed out that currently marketed cough-cold products may contain as many as 12 or more chemicals (including therapeutic ingredients and cosmetic chemicals such as flavors and dyes) and that the Panel recommended the continued marketing of products containing eight or more "active" chemicals. The comment argued that because most cough-cold drug products are combinations of a number of ingredients, their safety depends not only on the safety of individual ingredients for individual symptoms but also on the safety of the ingredients taken together. These ingredients, the comment stated, may interact with each other to enhance toxicity, inhibit effectiveness, or simply expose the consumer to unwanted side effects without providing an overriding benefit.

The agency disagrees with the comment's claim that the Panel endorsed combination products that did not meet "normal FDA standards." These standards are set forth in § 330.10(a)(4)(iv), which states that "an OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients, * * *" The Panel concurred with the requirements of the regulation that each active ingredient in a combination product must contribute to the claimed effects and must be necessary for the rational therapy of concurrent symptoms. The Panel was also aware of the inclusion of inactive (nontherapeutic) ingredients which are used for various purposes, such as preservatives and flavors, in cough-cold preparations. The Panel also recognized that some inactive ingredients may be necessary for marketing purposes (41 FR 38323). The Panel recommended that marketed products should contain only those active and inactive ingredients that are essential to the product.

The Panel evaluated the submitted data on active ingredients in combination products from the standpoint of safety and effectiveness and, based on its evaluation, recommended specific combinations of ingredients from the same and different pharmacologic groups. The Panel classified a number of combinations as Category II (41 FR 38326) and considered medical rationale and drug interactions in making these recommendations. For example, the Panel stated that combinations containing an anticholinergic and an expectorant are medically irrational because an expectorant promotes the production of secretions whereas the anticholinergic produces an opposite effect, i.e., antisecretory action.

After the Panel's report was published in September 1976, the agency published "General Guidelines for OTC Drug Combination Products" (Ref. 1). The guidelines outline the conditions for combinations of Category I active ingredients from the same and different therapeutic categories where each type of combination meets the OTC drug combination policy in all other respects. The guidelines also outline the conditions for the combination of Category I active ingredients from the same therapeutic category having the same or different mechanisms of action.

The agency believes that the Panel's recommendations and the agency's guidelines have adequately addressed the comment's concern as to the continued marketing of products containing several "active" chemicals and the safety of these ingredients when

taken together in a combination drug product.

Reference

(1) Food and Drug Administration "General Guidelines for OTC Drug Combination Products, September 1978," Docket No. 78D-0322, Dockets Management Branch.

33. One comment was opposed to OTC combination drug products because they contain fixed doses of ingredients and do not allow latitude for titrating the dose of the various ingredients. The comment cited one medical expert who stated that "fixed combinations prevent establishing an effective dose of individual constituents without affecting the dose of other ingredients (in the combination) * * * which not only may not be necessary, but which may cause undesirable toxic effects."

The comment also referred to a 1969 opinion of the National Academy of Sciences that "It is a basic principle of medical practice that more than one drug should be administered only for the treatment of a given condition only if the physician is persuaded that there is substantial reason to believe that each drug will make a positive contribution to the effect he seeks * * * each drug should be given at the dose level that may be expected to make its optimal contribution to the total effect, taking into account the status of the individual patient and any synergistic or antagonistic effects that one drug may be known to have on the safety or efficacy of the other."

The OTC combination drug products under consideration in this rulemaking are intended to relieve two or more concurrent symptoms. The convenience of being able to take one combination product instead of two or more single ingredient products appeals to many individuals. In fact, the Panel's report acknowledges that cough-cold combination drug products are widely used by consumers (41 FR 38322). Nevertheless, the agency recognizes that OTC combination drug products contain fixed doses of ingredients which do not allow the consumer to adjust the doses of the individual ingredients.

The agency believes that combinations of the cough-cold ingredients specified in this tentative final monograph provide a convenient and rational approach for relief of concurrent symptoms which so frequently accompany the common cold. The agency also believes that combination products formulated in accordance with the tentative final monograph will be safe and effective in a large percentage of the general population.

For consumers who do not believe that the doses of ingredients in fixed combinations represent the optimal titrations for them, the agency believes that appropriate single ingredient products will remain available.

34. One comment disagreed with what it described as the two ways in which the Panel justified its recommendation of cough-cold combinations: first, the requirement that each active ingredient belong to a different pharmacologic class; and second, the fact that "marketing experience" of cough-cold combination products showed that the incidence of consumer complaints for such products was relatively low. The comment contended that the Panel did not consider drug interactions when approving combinations which contain ingredients from different pharmacologic groups, e.g., nasal decongestant, expectorant, cough suppressant, etc. The comment also asserted that the fact that ingredients are added for different purposes is no assurance that they will not have a detrimental effect when combined. The comment further contended that "marketing experience" is worthless in determining the safety and effectiveness of combination products or any other products, because consumers cannot evaluate the special merits of each separate ingredient in the product and are unlikely to keep records and file complaints with the manufacturer.

The agency believes that the comment overlooks other important considerations in the Panel's evaluation of combinations. The Panel did not base its recommendation for cough-cold combinations on different pharmacological categories for each ingredient and marketing experience alone. The Panel specified that only one ingredient from a pharmacological category could be included in a combination and based its classification of the individual ingredients in combinations on data submitted to it for evaluation. It was not the Panel's intention to permit random combinations of ingredients in single products (a "shotgun" approach); however, because the symptoms of the common cold or hay fever often include nasal congestion, runny nose, and coughing, for example, the Panel believed it would be justifiable to combine active ingredients to treat these separate symptoms if the combination met the Panel's and the agency's requirements (41 FR 38323).

In its "General Guidelines for OTC Drug Combination Products" (cited above), published after publication of the Panel's report, the agency provided that Category I active ingredients from different therapeutic categories may be combined to treat different symptoms concurrently only if each ingredient is present within its established safe and effective dosage range and the combination meets the OTC drug combination policy in all other respects. The OTC drug combination policy, as stated in § 330.10(a)(4)(iv) of the OTC drug regulations, includes the provisions that combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients, and the combination provides rational concurrent therapy for a significant proportion of the target population.

The agency concludes that the Panel's Category I recommendations, as adopted by the agency, the application of the OTC drug regulations (21 CFR 330.10), and the agency's guidelines are adequate to insure that those combinations of ingredients permitted in the monograph would be generally recognized as safe, effective, and not misbranded. Regarding "marketing experience," the Panel considered marketing data submitted to it for review. The Panel indicated, based on the data, that there appeared to be a low incidence of adverse reactions. The Panel concluded, and the agency concurs, that while marketing data are limited and difficult to interpret they tend to support the safety of combinations of active ingredients reviewed by the Panel (41 FR 38325).

H. Comments on Specific OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Combination Drug Products

35. One comment requested that the agency not impose a limit on the number of ingredients from a single pharmacological group which may be combined in an OTC drug product. The comment contended that the Panel used purely theoretical reasons in categorizing combinations containing two ingredients from the same pharmacologic group as Category III and combinations containing more than two such ingredients as Category II. The comment stated that products combining multiple ingredients from a single pharmacologic group as well as from several pharmacologic groups have been widely sold for many years. The comment requested that the FDA's combination policy for OTC drug products in § 330.10(a)(4)(iv) be the governing criteria for these products without a limitation on the number of ingredients.

Section 330.10(a)(4)(iv) specifies the criteria for OTC combination drug

products. The agency's "General Guidelines for OTC Drug Combination Products" (cited above) state that ingredients from the same therapeutic category that have different mechanisms of action may be combined to treat the same symptoms or condition if the combination meets the OTC drug combination policy in 21 CFR 330.10(a)(4)(iv) in all respects and the combination is, on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose. The guidelines also state that Category I active ingredients from the same therapeutic category that have the same mechanism of action should not ordinarily be combined unless there is some advantage over the single ingredient in terms of enhancing effectiveness, safety, patient acceptance, or quality of formulation. Thus, the agency's combination policy does not set limits on the number of ingredients from the same pharmacologic group that may be combined, provided data are presented to show the combination meets the necessary criteria. Combinations containing ingredients from the same pharmacologic group will be permitted if adequate data are presented to the agency.

36. Several comments favored the Panel's recommendation to limit combination products to ingredients from three pharmacological groups. In addition, the comments stated that single ingredient products should be available to the consumer so that a specific drug can be used to treat a specific symptom without the consumer having to take unnecessary ingredients that may cause undesirable side effects.

Other comments disagreed with the Panel's proposal to limit combination products to ingredients from three pharmacological groups, arguing that this recommendation was an unscientific and arbitrary judgment inconsistent with the FDA guidelines for combination products (21 CFR 330.10(a)(4)(iv)), inconsistent with data submitted to the Panel on combination products containing ingredients from more than three pharmacological groups, and inconsistent with the Panel's allowance of Category I status for products containing ingredients from more than three pharmacological groups provided a suitable target population can be identified. One comment stated that the requirement that additional evidence that a significant target population exists for a combination containing ingredients from four pharmacologic groups is unwarranted, and that the imposition of a limit of a specific number of ingredients may curtail the flexibility of the formulator and frustrate the principle of combination products. Several comments recommended that no fixed limit be placed upon the number of active ingredients in a combination if the combination can be shown to be a rational, safe, and effective combination with a suitable target population.

The agency agrees that no fixed limit need be placed upon the number of active ingredients in a combination product if it can be shown to be a rational, safe, and effective combination with a suitable target population. This position is consistent with the FDA policy for OTC drug combination products in 21 CFR 330.10(a)(4)(iv) and with the "General Guidelines for OTC Drug Combination Products" (cited above). The Panel placed certain two and three ingredient combination products in Category I because data were presented to support their safety and effectiveness. The agency will consider any combination for Category I, regardless of the number of ingredients, provided adequate data are presented in accordance with the regulation and guidelines mentioned above.

The agency also agrees that single ingredient products are desirable and should be available. However, the agency recognizes that a significant target population exists for some OTC cough-cold combination products to treat concurrent symptoms and has proposed that such combinations be classified as Category I. Allowable combinations are listed in § 341.40 of the tentative final monograph.

37. One comment disagreed with the Panel's conclusions on combining active ingredients from the same pharmacological group at less than the minimum effective dose. The comment contended that requiring such combinations to show some special benefit is not in accord with the FDA policy for combination products (21 CFR 330.10(a)(4)(iv)). The comment recommended that such combinations not be required to show some special benefit beyond substantial support of safety and effectiveness.

After the Panel's report was published, the agency developed its "General Guidelines for OTC Drug Combination Products" (cited above). In part, the guidelines pertain to the combination of two or more active ingredients from the same pharmacological (therapeutic) category that have the same or different mechanisms of action. Paragraph 3 of the guidelines provides that "Category I active ingredients from the same therapeutic category that have the same mechanism of action should not ordinarily be combined unless there is some advantage over the single ingredients in terms of enhanced effectiveness, safety, patient acceptance, or quality of formulation. They may be combined in selected circumstances to treat the same symptoms or conditions if the combination meets the OTC combination policy (in § 330.10(a)(4)(iv)) in all respects, the combination offers some advantage over the active ingredients used alone, and the combination is, on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose." Paragraph 2 of the guidelines provides that: "Category I active ingredients from the same therapeutic category that have different mechanisms of action may be combined to treat the same symptoms or condition if the combination meets the OTC combination policy in all respects and the combination is on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose. Such combinations may utilize each active ingredient in full therapeutic dosage or sub-therapeutic dosage, as appropriate."

The agency developed these guidelines to clarify the existing regulation in 21 CFR 330.10(a)(4)(iv). Both the guidelines and the regulation will be used in evaluating data regarding combination products. The comment did not present any data that would lead the agency to change its general guidelines for OTC drug combination products described above.

38. One comment pointed out an error at 41 FR 38326 concerning combinations containing an antitussive and a local anesthetic or a local analgesic-antipyretic as a lozenge, and combinations containing a nasal decongestant and a local anesthetic or a local analgesic-antipyretic as a lozenge. The comment stated that the word "antipyretic" should be deleted from these statements because the "compounds" being referred to in these combinations are not antipyretics.

The agency points out that the Panel did not include the word "antipyretic" in § 341.40 (j) and (o) of its recommended monograph, which correspond to the statements at 41 FR 38326 cited by the comment. It appears that the word "antipyretic" was erroneously included at 41 FR 38326 and that the Panel intended the statements on that page to be consistent with its recommended

monograph. The Panel's report at 41 FR 38326 is amended accordingly.

39. One comment suggested that § 341.40 (j) and (o) in the advance notice of proposed rulemaking do not accurately reflect the intent of the Panel. The comment pointed out that § 341.40(j) permits combining any single Category I antitussive active ingredient with any single generally recognized as safe and effective local anesthetic or local analgesic active ingredient and that § 341.40(o) permits combining any single Category I nasal decongestant active ingredient with any single generally recognized as safe and effective local anesthetic or local analgesic active ingredient. The comment argued that not all topical analgesic ingredients that are generally recognized as safe and effective should be used on the oral mucosa and that the Panel actually intended to permit combinations of an antitussive or nasal decongestant ingredient with any ingredient that is generally recognized as safe and effective for the relief of sore throat pain.

The comment also indicated that the monograph for OTC oral cavity drug products [which has been renamed oral health care drug products] will determine which pharmacologic categories and ingredients are generally recognized as safe and effective for the relief of sore throat pain and that ingredients from pharmacologic groups other than analgesics, e.g., demulcents, may be appropriate. The comment therefore recommended that paragraphs (j) and (o) of § 341.40 be revised to provide for combinations of an antitussive or a nasal decongestant ingredient with any single ingredient from any pharmacologic group which is designated in the monograph for OTC oral cavity drug products as being generally recognized as safe and effective for the relief of sore throat pain. In addition, the comment suggested that § 341.40(o) be limited specifically to oral nasal decongestant ingredients because § 341.40(o), as currently written, permits combining a topical nasal decongestant with a local anesthetic active ingredient.

In the first segment of the tentative final monograph for OTC oral health care drug products, published in the **Federal Register** of January 27, 1988 (53 FR 2436), the agency deferred consideration of the following combinations to this tentative final monograph: Expectorants and demulcents; expectorants and oral anesthetic/analgesics; oral nasal decongestants and demulcents, oral anesthetic/analgesics, or antimicrobials; antihistamines and oral anesthetic/analgesics, antimicrobials, astringents, debriding agent/oral wound cleansers, or demulcents; and oral antitussives and oral anesthetic/analgesics, antimicrobials, astringents, debriding agent/oral wound cleansers, or demulcents.

The agency agrees with the comment that combinations containing a single antitussive or nasal decongestant ingredient and a single local anesthetic or local analgesic ingredient should be limited to those anesthetic/analgesic ingredients which are generally recognized as safe and effective for use on the oral mucosa. Such ingredients have been proposed in § 356.10 of the tentative final monograph for OTC oral health care drug products (53 FR 2458). To be consistent with the language used in the oral health care drug products tentative final monograph, the term "oral anesthetic/analgesic" is used in this document rather than the term "local anesthetic or local analgesic."

In addition, the agency concurs with the comment's suggestion that § 341.40(o) be restricted to oral nasal decongestants. The agency believes that such a restriction was originally intended by the Panel because it indicated that such a combination should be used only in lozenge form. Topical nasal decongestants are intended for application directly to the nasal mucosa while oral nasal decongestants act through systemic absorption. Antitussives and bronchodilators may also be used as oral or topical drugs. Therefore, for clarity, the agency is specifying in the monograph in § 341.40 and § 341.85 whether antitussives, bronchodilators, and nasal decongestants are for oral or topical (i.e., inhalant or ointment) use.

The comment requested a Category I classification for combination drug products containing an antitussive or a nasal decongestant ingredient with any generally recognized safe and effective ingredient for sore throat pain. In this tentative final monograph the agency evaluates the comments requested combination drug products and other cough-cold and oral health care combination drug products which were deferred from the oral health care rulemaking to the cough-cold rulemaking.

The combination of a local anesthetic or local analgesic (oral anesthetic/analgesic) with an oral antitussive or an oral nasal decongestant was placed in Category I by the Cough-Cold Panel provided that the product is available in the form of a lozenge (41 FR 38326). The agency agrees with the Panel.

In addition, the agency believes that a demulcent can be combined with an oral antitussive or an oral nasal decongestant in a solid dosage form. In several submissions to the Cough-Cold Panel, the demulcent attributes of the products were mentioned (Ref. 1). The Oral Cavity Panel's definition of a demulcent is that it is a bland, inert agent that soothes and relieves irritation of inflamed or abraded surfaces such as mucous membranes. An anesthetic blocks pain receptors resulting in a sensation of numbness and abolition of response to painful stimuli (47 FR 22927). Dry or sore throat is a generally recognized symptom of the common cold (Refs. 2 and 3). In discussing combination drug products containing local anesthetics or other agents for the relief of sore throat, the Cough-Cold Panel stated that because symptoms of sore throat often accompany cough and the "common cold," combination drug products containing cough-cold ingredients and agents to relieve minor irritations are rational (41 FR 38325).

The Cough-Cold Panel reviewed data relating to combination products containing cough-cold ingredients and oral health care ingredients with claims for relief of sore throat. The majority of these data concerned anesthetic/analgesics combined with cough-cold ingredients. The Panel determined that products containing an antitussive or a nasal decongestant combined with an oral anesthetic/analgesic in a lozenge dosage form are rational, identified a target population that would benefit from such products, and placed such combinations in Category I (41 FR 38325). The Panel did not do an extensive review of all possible oral health care and cough-cold combination drug products; thus, it did not identify any other specific cough-cold and oral health care combination products as meeting its requirements for Category I classification. The Panel established specific criteria for the treatment of symptoms with combination products and based its Category I recommendations on whether the combination product is rational concurrent therapy for a significant and existing target population that can benefit from such use (41 FR 38322). Similarly, justification for classifying a 4-ingredient combination product was based on these principles, i.e., identification of a significant target population that required treatment for concurrent symptoms (see comment 47 below). Because of the similarities in the use of oral anesthetic/analgesics and oral demulcents in relieving pain and irritation, the agency believes that the

target populations for products containing an oral nasal decongestant or an oral antitussive combined with an oral anesthetic/analgesic would be the same as that for combination products containing an oral nasal decongestant or an oral antitussive combined with a demulcent ingredient. In addition, in § 356.20(b) of the tentative final monograph for OTC oral health care drug products (January 27, 1988; 53 FR 2458), the agency proposed that an oral anesthetic/analgesic and an oral demulcent was an acceptable combination. Therefore, the agency is proposing that an oral nasal decongestant and/or an oral antitussive can be combined with an oral anesthetic/analgesic and an oral demulcent. The Cough-Cold Panel recognized that most sore throat remedies are applied topically while other symptoms of the cold are usually treated internally by products ingested orally (41 FR 38325). Thus, the type of epidemiological data considered acceptable by the Panel to place a combination of an oral antitussive or oral nasal decongestant and an oral anesthetic/analgesic in Category I can be extrapolated to allow a demulcent or a demulcent and anesthetic/analgesic combination to be combined with similar cough-cold ingredients. Therefore, the agency is classifying in Category I in this tentative final monograph the following combinations provided the product is in a solid dosage form to be dissolved in the mouth and swallowed: (1) An oral antitussive or an oral nasal decongestant and an oral anesthetic/analgesic, (2) an oral nasal decongestant, an oral antitussive, and an oral anesthetic/analgesic, (3) an oral antitussive or an oral nasal decongestant and an oral demulcent, (4) an oral nasal decongestant, an oral antitussive, and an oral demulcent, (5) an oral antitussive or an oral nasal decongestant, an oral anesthetic/analgesic, and an oral demulcent, and (6) an oral nasal decongestant, an oral antitussive, an oral anesthetic/analgesic, and an oral demulcent.

In its report on OTC oral health care drug products, the Oral Cavity Panel classified the combination of an expectorant with an anesthetic/analgesic in Category II because it believed that an anesthetic would be diluted and removed from the mucous membranes of the mouth and throat by the action of the expectorant (47 FR 22792). However, the final monograph for OTC expectorant drug products, to be published in a future issue of the **Federal Register**, will provide for expectorants to be taken orally to promote or facilitate the removal of secretions from the respiratory airways. Further, the indications for expectorants are "helps loosen phlegm (sputum) and bronchial secretions and rid the bronchial passageways of bothersome mucus" or "drain bronchial tubes by thinning mucus." Thus, contrary to the Oral Cavity Panel's statements, the expectorant ingredient included in the monograph is not intended to exert an effect in the mouth and throat, but is intended to have a systemic effect. It could be expected that when a combination drug product in a solid dosage form containing an expectorant and an oral anesthetic/analgesic or a combination containing an expectorant and an oral demulcent is dissolved in the mouth and then swallowed, the oral anesthetic/analgesic or the oral demulcent will have exerted its topical therapeutic effect before the expectorant exerts its systemic effect. Therefore, in such combination drug products, the action of the expectorant would not interfere with the sore throat relief provided by the anesthetic/analgesic or the demulcent ingredient; thus, the agency believes that the combination of an expectorant with an oral anesthetic/analgesic in a solid dosage form and the combination of an expectorant and an oral demulcent in a solid dosage form could be rational. A product containing an expectorant and an anesthetic/analgesic was submitted to the Cough-Cold Panel, but the product is no longer marketed (Ref. 4). The agency is not aware of any currently marketed products containing these combinations of ingredients in a solid dosage form. Moreover, no data were submitted to demonstrate a significant target population with concurrent symptoms that would benefit from such combinations. Therefore, the agency is proposing a Category III classification in this tentative final monograph for the combination of an expectorant with an oral anesthetic/analgesic and the combination of an expectorant with an oral demulcent in a solid dosage form.

Likewise, the agency believes that the combination of an antihistamine and an oral anesthetic/analgesic or an oral demulcent could be rational if the combination drug product is in a solid dosage form so that the anesthetic/analgesic ingredient or the demulcent ingredient may exert its topical effect and the antihistamine can be ingested. The symptoms of allergic rhinitis and minor throat irritation that may result from the nasal congestion that often occurs with allergic rhinitis and subsequent breathing through the mouth could be treated concurrently by a combination drug product containing an antihistamine and an oral health care active ingredient. However, the agency is not aware of any currently marketed OTC drug products that contain such a combination of ingredients, and no data were submitted to demonstrate a significant target population with concurrent symptoms that would benefit from such combinations. Therefore, the agency is proposing a Category III classification in this tentative final monograph for the combination of an antihistamine with an oral anesthetic/analgesic and the combination of an antihistamine and an oral demulcent.

The agency has considered the combination of a debriding agent/oral wound cleanser with an antitussive or antihistamine active ingredient. The Oral Cavity Panel classified several combinations containing debriding agents in Category II stating that a debriding agent, because of its mechanical cleansing action, would wash away or dilute the other active ingredients in the combination and thus prevent them from acting as intended or from exerting their therapeutic effects (47 FR 22792). In addition, in the first segment of the tentative final monograph for OTC oral health care drug products, the agency proposed a Category II classification for the combination of a debriding agent/oral wound cleanser and a demulcent (53 FR 2452). The agency notes that a debriding agent/oral wound cleanser is designed to be swished around in the mouth for at least a minute and then spat out; it should not be swallowed. In a combination drug product containing a debriding agent/oral wound cleanser and an antitussive or an antihistamine, the antitussive or antihistamine could not exert its therapeutic effect because it would not be ingested. The agency concludes that the combination of a debriding agent/oral wound cleanser with an oral antitussive or an antihistamine is not rational. Therefore, the agency is proposing a Category II classification for the combination of a debriding agent/oral wound cleanser with an antitussive or an antihistamine.

Regarding the combination of an oral health care astringent with an oral antitussive or an antihistamine, the agency notes that, as is the case for debriding agent/oral wound cleansers, the directions for an astringent require that the ingredient be in the mouth for at least one minute and then spat out. The agency concludes that these directions are incompatible with the effective use of an oral antitussive or an antihistamine active ingredient. Therefore, in this tentative final

monograph the agency is proposing a Category II classification for the combination of an astringent with an oral antitussive or an antihistamine.

Because the Oral Cavity Panel did not propose any Category I indications for oral antimicrobials, the agency will discuss combinations that include oral antimicrobials in the antimicrobial segment of the tentative final monograph for OTC oral health care drug products, to be published in a future issue of the **Federal Register**. If necessary, the cough-cold combinations tentative final monograph will be amended at a later date to include any combinations identified as being Category I.

Accordingly, in this tentative final monograph, proposed § 341.40(j) reads as follows: "Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.10 provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed," and § 341.40(p) reads as follows: "Any single oral nasal decongestant active ingredient identified in § 341.20(a) may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.10 provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed."

In addition, the agency is adding the following Category I combinations to the designated paragraphs in § 341.40:

(u) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral demulcent active ingredient identified in § 356.18 provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed.

(v) Any single oral nasal decongestant active ingredient identified in § 341.20(a) may be combined with any single oral demulcent active ingredient identified in § 356.18 provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed.

(w) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any single oral demulcent active ingredient identified in § 356.18 provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed.

(x) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.10 and any single oral demulcent active ingredient identified in § 356.18 provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed.

(y) Any single oral nasal decongestant active ingredient identified in § 341.20(a) may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.10 and any single oral demulcent active ingredient identified in § 356.18 provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed.

(z) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any single oral anesthetic/analgesic active ingredient identified in § 356.10 and any single oral demulcent active ingredient indentified in § 356.18 provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed.

References

(1) OTC Volumes 040061, 040104, and 040248.

(2) "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association, Washington, pp. 127, 130, and 131, 1986.

(3) Berkow, R., editor, "The Merck Manual of Diagnosis and Therapy," 14th Ed., Merck and Co., Rahway, NJ, p. 189, 1982.

(4) OTC Volume 040104.

40. One comment noted a possible oversight in the Panel's classification of Category I combinations. The comment pointed out that the Panel placed in Category I combinations containing an antitussive and a local anesthetic or local analgesicantipyretic in a lozenge dosage form and combinations containing a nasal decongestant and a local anesthetic or local analgesic-antipyretic in a lozenge dosage form. The Panel did not, however, classify combinations of an antitussive, a nasal decongestant, and a local anesthetic or local analgesic-antipyretic. The comment requested Category I classification of such combinations in a lozenge dosage form, stating that there should be no difficulty in recognizing the target population with concurrent symptoms necessitating treatment with the three pharmacologically different Category I ingredients.

The agency has reviewed the Panel's recommended criteria for classifying cough-cold combinations and agrees that there is a target population that has the symptoms of nasal congestion, cough, and sore throat concurrently. As noted in comment 38 above, the term "antipyretic" should not be included for combinations such as these. As noted in comment 39 above, the anesthetic/analgesic ingredients in these combinations are limited to those that are generally recognized as safe and effective for use on the oral mucosa, and the nasal decongestants in these combinations are limited specifically to any oral nasal decongestants that are identified in § 341.20(a) as generally recognized as safe and effective (50 FR 2238). The agency is including in this tentative final monograph combinations containing an oral antitussive, an oral nasal decongestant, and an anesthetic/analgesic provided the product is available only in a solid dosage form to be dissolved in the mouth and swallowed.

41. One comment opposed the Panel's Category II classification of a combination product containing an antihistamine for the exclusive purpose of sedation and a second antihistamine for relief of the symptoms of allergic rhinitis. The comment referred to the Panel's discussion regarding nighttime cough-cold products which are promoted for use at bedtime to provide a restful sleep (41 FR 38415, paragraph B.1.a). The Panel stated that the duration of drug effects in nighttime cold products which are recommended to be taken once at bedtime is not fully documented, and it recommended the use of antihistamines in cough-cold products only for the relief of symptoms of allergic rhinitis. The comment contended that the Panel's determination that a combination of two antihistamines is "not rational" is a "conclusionary statement" and that the Panel provided no data to support this conclusion. The comment recommended that such combinations be placed in Category I in the absence of any supporting data to prove irrationality.

The agency agrees with the Panel that it is irrational to add an additional antihistamine primarily for the purpose of sedation when treating the symptoms of allergic rhinitis. When using an antihistamine to relieve the symptoms of allergic rhinitis, the desired therapeutic effect is to alleviate the symptoms of allergy, i.e., runny nose, sneezing, and itchy and watery eyes. Addition of a second antihistamine to the product to promote sleep is unnecessary because if allergic rhinitis symptoms are relieved at night by using an antihistamine, most individuals will sleep normally. Antihistamines as a class produce varying degrees of drowsiness as a side effect. The agency is not convinced that there is a need to compound the drowsiness effect of one antihistamine

by adding a second antihistamine to the product. The comment also implies that there is a target population for which an OTC drug product consisting of two antihistamines would be appropriate. However, the comment did not submit any supporting data. For these reasons, the combination of an antihistamine for the relief of the symptoms of allergic rhinitis and an antihistamine added solely for sedation purposes remains in Category II.

42. One comment expressed concern that adverse reactions have been reported with some antihistamine/decongestant combination products containing central nervous system stimulants or sympathomimetic-like agents. The comment stated that good data are not available concerning adverse reactions caused by such combinations; therefore in-depth review is needed. No additional information was submitted by the comment.

The agency notes that the Panel reviewed the available data to determine the rationale and appropriateness of cough-cold combination drug products and to determine the potential for these combinations to cause side effects and adverse reactions. Based on its review, the Panel recommended that any Category I antihistamine could be combined with any Category I nasal decongestant provided each ingredient in the combination was present in amounts within the effective dosage range and the appropriate Category I labeling was used (41 FR 38326).

The data reviewed by the Panel included the marketing history and adverse reaction reports (Ref. 1) for currently marketed drug products containing antihistamines and nasal decongestants. The Panel found that these data showed a low incidence of adverse effects for these combinations (41 FR 38325) and therefore did not recommend any additional warning statements beyond those recommended for individual antihistamine and oral nasal decongestant active ingredients. The agency has reviewed the adverse reaction reports for the years 1969 to 1988 for various combination drug products containing antihistamines and nasal decongestants. These data show that there is a relatively low incidence of central nervous system stimulant adverse effects caused by these combinations (Ref. 2).

Because the pharmacologic actions of the various Category I antihistamines are similar, and because the pharmacologic actions of the various Category I oral nasal decongestants are similar, the agency agrees with the Panel that any Category I antihistamine and any Category I oral nasal decongestant may be safely combined. All warning statements that are required for individual antihistamine and oral nasal decongestant active ingredients will be required for combination drug products containing those ingredients, and the agency believes that the proposed warnings in §§ 341.72(c) and 341.80(c) are adequate to warn consumers of the possibility of adverse effects of a combination product. Therefore, no further in-depth review is necessary at this time.

References

(1) OTC Volumes 040287 and 040287A.

(2) Department of Health and Human Services, Food and Drug Administration, "Annual Adverse Reaction Summary Listing," pertinent pages for the years 1969 to 1988, OTC Volume 04GTFM, Docket No. 76N-052G, Dockets Management Branch.

43. One comment argued that it was inappropriate for the Panel to recommend a Category II classification for a combination containing a drug recognized as both an antitussive and an antihistamine combined with another antitussive and/or antihistamine. The comment argued that the Panel expressed only theoretical concerns regarding the safety of this combination and did not document the incidence of side effects it envisaged as occurring. The comment urged that such a combination be placed in Category III.

The agency believes that the combination drug products described by the comment and classified by the Panel in Category II (41 FR 38326) should be considered to be combinations containing two ingredients from the same pharmacologic group and that a Category II classification is inconsistent with the Panel's recommendation that such combinations containing two ingredients from the same pharmacologic group should be in Category III. The agency's "General Guidelines for OTC Drug Combination Products" (cited above), which were made available after publication of the Panel's report, state that Category I active ingredients from the same therapeutic category that have the same mechanism of action should not ordinarily be combined unless there is some advantage over the single ingredients in terms of enhanced effectiveness, safety, patient acceptance, or quality of formulation. However, these guidelines also state that such ingredients may be combined in selected circumstances to treat the same symptoms or conditions if the combination meets the OTC drug combination policy in all respects, the combination offers some advantage over the active ingredients used alone, and the combination is, on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose. Accordingly, based on the Panel's position concerning combinations containing two ingredients from the same pharmacologic group and the agency's general combination guidelines, the agency has placed these types of oral antitussive-antihistamine combinations in Category III.

44. One comment was opposed to the proposed restriction of OTC antitussive-antihistamine combinations to nonproductive cough when the underlying disease stimulating the cough is a cold. The comment stated that it was not aware of any "evidence that the combining of OTC doses of antitussives and antihistamines results in any negative effect on patients with productive cough due to a cold." The comment contended that consumer and clinical experience, including clinical studies reported to the Panel, provided evidence that the use of antitussive-antihistamine combinations for cough due to a cold are both safe and beneficial to the patient.

The agency does not agree with the comment that antitussive-antihistamine combinations should be allowed as a treatment for productive cough, i.e., cough associated with excessive phlegm, when the underlying disease stimulating the cough is a cold. Antitussives, as single ingredient products, have also been restricted to non-productive cough (i.e., cough that is not associated with excessive secretions) because cough suppression in certain diseases with productive cough may impair clearing of the airway (48 FR 48589). Antihistamines have a drying effect and may cause thickening of the secretions in the larynx, pharnyx, and lower respiratory tract. Retention of these secretions may also lead to the potentially harmful effect of airway obstruction (Ref. 1). A productive cough may be associated with a wide variety of diseases, ranging from a mild self-limiting disease to a very serious disease (Ref. 1). The symptoms of the common cold in its early stages are very similar to the early stages of diseases such as pneumonia, tuberculosis, pertussis, or measles, and are not readily distinguishable (Refs. 2, 3, and 4). It is not possible for the consumer to recognize the cause of a productive cough, and the agency believes that, in the interest of safety, a generalized warning against use of antitussives in cough accompanied by excessive phlegm (mucus) is warranted.

The Panel recommended the following warning in § 341.74(b)(2) for all products containing an antitussive: "Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or where cough is accompanied by excessive secretions except under the advice and supervision of a physician." This warning (redesignated as § 341.74(c)(1)(i) in the antitussive tentative final monograph (48 FR 48594)) has been slightly revised for clarity to read as follows:

Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.

References

(1) Calvert, J.C., "Cough Differential Diagnosis and Treatment," *Drug Intelligence and Clinical Pharmacy*, 10:640–650, 1976.

(2) Keefer, C.S., and R.W. Wilkins, editors, "Medicine-Essentials of Clinical Practice," Little, Brown and Co., Boston, pp. 103, 113, 125, and 127, 1970.

(3) Conn, H.F., and R.B. Conn, Jr., editors, "Current Diagnosis," W.B. Saunders Co., Philadelphia, pp. 116 and 180, 1974.

(4) Talso, P.J., and A.P. Remenchik, editors, "Internal Medicine Based on Mechanisms of Disease," C.V. Mosby Co., St. Louis, pp. 382 and 394, 1968.

45. One comment pointed out a discrepancy between the Panel's report and the Panel's recommended monograph regarding the combination of an oral bronchodilator and an antitussive. The comment stated that the Panel indicated in its report that a combination product containing an oral bronchodilator and an antitussive when labeled only for cough associated with asthma is a Category II combination because the antitussive suppresses cough, and the cough reflex is essential in asthma to maintain an open airway by clearing the respiratory passages of excessive secretions. However, such a combination was included as a Category I combination in § 341.40(f) and § 341.85(b) of the advance notice of proposed rulemaking.

The agency previously recognized this discrepancy and corrected it in the Federal Register of October 28, 1977 (42 FR 56756) by proposing to delete § 341.40(f) and § 341.85(b). Interested persons were invited to comment on this proposed deletion, but no comments were received. Therefore, the combination of an oral bronchodilator and an oral antitussive labeled for cough associated with asthma is classified as Category II and is not included in this tentative final monograph.

46. One comment disagreed with the Panel's recommendation that a combination containing an antitussive and an expectorant that is labeled for a productive cough be placed in Category III and requested that such a combination be classified in Category I. The comment agreed with what it contended was the Panel's concern that chronic bronchitic, asthmatic, and emphysematous patients not drown in their own secretions when taking such a combination, but argued that this is not a problem with OTC use of this combination. The comment claimed that: (1) OTC antitussives at their recommended dosages do not prevent physiological coughing, i.e., coughing to clear the airways of mucus, but merely reduce excessive irritative cough; (2) there is no evidence that increasing the volume of mucus in productive cough due to a cold by the action of an expectorant represents a hazard to a person with a cold; and (3) when the recommended use of the combination is for cough due to a cold, the great majority of the population desiring cough relief do not have bronchitis, asthma, or emphysema. The comment stated that there is a growing body of clinical acceptance that OTC antitussives reduce excessive irritative cough but not physiological coughing and therefore would not present a problem in patients with productive cough. It also stated that clinical studies of cough syrups containing antitussives and expectorants in patients with cough due to a cold have usually involved patients with productive and nonproductive cough indiscriminately, without evidence of lack of safety.

The Panel specifically stated that "additional studies are necessary to assess the combined effects of an antitussive and an expectorant in the presence of excessive or more fluid bronchial secretions" (41 FR 38328). Accordingly, the Panel concluded that an OTC cough-cold combination of an antitussive and an expectorant, when indicated for a productive cough, be classified in Category III. The agency agrees with the Panel's conclusion and does not consider the information contained in the comment sufficient to support a Category I classification for a combination of an oral antitussive and an expectorant. The comment failed to provide specific documentation, in the form of data from well-controlled clinical studies, to justify its claims. Without such data, the agency concludes that a combination containing an oral antitussive and an expectorant labeled for productive cough will not be reclassified to Category I and will remain in Category III.

47. One comment objected to the Panel's decision to place combination drug products containing ingredients from four different pharmacologic groups in Category III until a significant target population requiring such a combination was identified and argued that data were submitted to the Panel concerning the existence of such a population (Ref. 1). Another comment submitted new data from an unpublished epidemiological study (Ref. 2) conducted to comply with the Panel's recommendation that a significant target population be identified for an OTC four-ingredient combination drug product containing an analgesic-antipyretic, an antitussive, an antihistamine, and a nasal decongestant for treatment of concurrent cold symptoms (41 FR 38328). Six comments, noting that the Panel did not categorize a combination consisting of ingredients from three of the four pharmacologic groups, i.e., an analgesic-antipyretic, an antihistamine, and a nasal decongestant, requested that this three-ingredient combination be classified in Category I, based on submissions made for the combination containing ingredients from the four pharmacologic groups (Ref. 3).

The data referred to by the first comment included several literature references, a consumer research study, and a retrospective analysis of four clinical studies, none of which was originally conducted to determine the existence of the applicable target population. The Panel concluded that these data did not support the existence of a significant target population with concurrent cold symptoms of sufficient duration and severity to require a four-ingredient combination drug product.

The new data submitted by the second comment consisted of an epidemiological study conducted by seven investigators who followed a protocol consisting of a physical examination, including a nasal turbinate observation; a characterization of complaints; and a retrospective survey of subjects who had head colds and had been accepted for pharmacological assay experiments. The agency's analysis of the data indicated that the seven investigators identified a total of 695 patients, of whom 308, or 44.32 percent, had symptoms in all four treatment categories, i.e., (1) analgesic-antipyretic for pain, such as muscle ache and headache, and fever; (2) antitussive for wet or dry cough; (3) antihistamine for watery eyes, runny nose, and itchy nose; and (4) nasal decongestant for congestion. The retrospective survey confirmed the epidemiological study by identifying another large population of

individuals with symptoms in all four categories.

The agency accepts the results of the epidemiological study as evidence of the existence of a significant target population with concurrent cold symptoms of sufficient duration and severity to require a combination product containing an analgesic-antipyretic (as a single ingredient identified in § 343.10 or as a combination containing an analgesic-antipyretic identified in § 343.20 (a) or (b)(3), an oral antitussive, an antihistamine, and an oral nasal decongestant. Based on this evidence, the agency proposes to reclassify such a combination from Category III to Category I in this tentative final monograph.

Based on its evaluation of the data submitted for use of a combination product containing ingredients from the four pharmacological groups, the agency proposes to classify the following as Category I in this tentative final monograph: (1) a combination consisting of an analgesic-antipyretic (as a single ingredient or as a combination containing an analgesic-antipyretic as identified above), an oral antitussive, and an oral nasal decongestant and (2) a combination consisting of an oral antitussive and an analgesic-antipyretic (as a single ingredient or as a combination containing an analgesic-antipyretic as identified above). The agency's detailed comments and evaluation on the data are on file in the Dockets Management Branch (Refs. 4 and 5).

The labeling for the analgesic-antipyretic component of combination drug products containing cough-cold ingredients and analgesic-antipyretic ingredients may include indications for the "temporary relief of minor aches, pains, headache, muscular aches, and fever associated with the common cold." (See comment 61 below.) These indications, consistent with the symptoms reported in the epidemiological study (Ref. 2), are commonly found on currently marketed products and are also consistent with the intended use of a combination drug product containing cough-cold and analgesic-antipyretic ingredients.

References

(1) Comment No. C0111, Docket No. 76N-0052, Dockets Management Branch.

(2) Comment No. C0180, Docket No. 76N-0052, Dockets Management Branch.

(3) Comment Nos. C0109, C0110, C0134, C0144, C0161, C0188, Docket No. 76N-0052, Dockets Management Branch.

(4) Letter from W.E. Gilbertson, FDA, to G.F. Hoffnagle, Richardson-Vicks, Inc., coded LET077, Docket No. 76N-052G, Dockets Management Branch.

(5) Letter from W.E. Gilbertson, FDA, to B.M. Lanman, Bristol-Myers Products, Division of Bristol-Myers Co., coded LET078, Dockets No. 76N-052G, Dockets Management Branch.

48. One comment suggested that the list of ingredients deferred to the Advisory Review Panel on OTC Oral Cavity Drug Products (Oral Cavity Panel) (41 FR 38319) should be supplemented to include benzocaine. The comment pointed out that there are several currently marketed combination drug products containing benzocaine and an antitussive or a nasal decongestant and that such combinations have been classified as Category I by the Cough-Cold Panel (41 FR 38326).

Benzocaine was reviewed and included in the Oral Cavity Panel's report published in the **Federal Register** of May 25, 1982 (47 FR 22712). Benzocaine should have been listed at 41 FR 38319 with the other ingredients deferred by the Cough-Cold Panel to the Oral Cavity Panel, and the agency now corrects the omission.

49. One comment objected to the Panel's classification of phenobarbital 8 mg in Category III as a stimulant corrective to counteract the adverse central nervous system stimulant effects of drugs such as ephedrine in antiasthmatic preparations and requested Category I classification instead. The comment cited Goodman and Gilman (Ref. 1), as reflecting the experience of clinicians, to support its contention that there are sufficient data to permit final classification of phenobarbital as safe and effective for OTC use as a stimulant corrective. The comment presented the following medical arguments to justify the use of phenobarbital at a low dose to counteract the central nervous system stimulant effects of other drugs: (1) Barbiturates are respiratory depressants, (2) the hypoxic and chemical drives to respiration are decreased as the barbiturate dose increases, and (3) the medical treatment of asthma must provide for maximum breathing capacity and velocity of air movement, especially in the expiratory phase. In addition, the comment noted that the Panel used the term "sedative corrective" instead of "stimulant corrective" in its statement on the effectiveness of phenobarbital (41 FR 38418).

The agency has reviewed the Panel's recommendations on phenobarbital (41 FR 38417) and on combination products containing stimulant and sedative correctives (41 FR 38325), as well as the information provided in the comment. The agency has also reviewed the findings of the Pulmonary-Allergy Drugs Advisory Committee, which stated unanimously that there was no evidence that formulation with a barbiturate reduces the incidence of side effects caused by ephedrine-theophylline combinations (Ref. 2).

Sims, do Pico, and Reed (Ref. 3) reported in a recent double-blind, randomized, placebo-controlled study that phenobarbital 8 mg, in combination with theophylline 130 mg and ephedrine 25 mg, did not reduce the central nervous system stimulant side effects of tremor, nervousness, or nausea induced by theophylline or ephedrine. As the Panel noted, phenobarbital and other barbiturates are subject to abuse (41 FR 38417), phenobarbital is a potent hepatic microsomal enzyme-inducer which alters corticosteroid metabolism (prescription corticosteroid drugs are sometimes used in patients with bronchial asthma), and phenobarbital has a known enzyme-inducing effect with many other commonly used drugs (Refs. 4, 5, and 6).

As indicated in the comment, phenobarbital and the barbiturates have a respiratory depressant effect, which would be a specific hazard to a large segment of the population with diminished pulmonary function as a result of chronic obstructive pulmonary disease, and a possible hazard to individuals with other diseases.

These adverse effects could occur with the proposed adult oral dosage regimen of 8 to 16 mg of phenobarbital every 4 hours (41 FR 38418). The daily (24 hour) dose of phenobarbital could be as high as 96 mg. Lecamwasam et al. (Ref. 5), Landay et al. (Ref. 6), and Brooks et al. (Ref. 7) have reported significant effects of phenobarbital on the metabolism of other drugs when administered at a level of 90 mg daily. Thus, phenobarbital used at this dosage could create the potential for a significant incidence of adverse drug interactions by affecting the metabolism of many other commonly used drugs.

Goodman and Gilman (Ref. 1), whom the comment cited, state that "the central nervous system stimulant action of ephedrine tends to cause wakefulness and irritability, and a barbiturate is commonly given in addition." However, the "reference" in Goodman and Gilman does not provide any indication of a phenobarbital dosage for this purpose, nor does it indicate that phenobarbital should be used in combination with ephedrine or theophylline for self-medication. On the contrary, Goodman and Gilman state that barbiturates in

mixtures offer little advantage and that the physician should prescribe such drugs separately for concurrent use, adjusting doses to specific patient needs (Ref. 8). In fact, data show that phenobarbital 8 mg is not effective as a stimulant corrective in combination with ephedrine and theophylline (Ref. 2).

Based on its review of available data, the agency concludes that phenobarbital is not generally recognized as safe and effective for OTC use as a stimulant corrective in combination products with central nervous system stimulant drugs such as ephedrine or the theophyllines and is reclassifying phenobarbital 8 mg as a stimulant corrective from Category III to Category II.

Regarding the use of the term "sedative corrective" in the Panel's report at 41 FR 38325, the agency agrees with the comment that the term "stimulant corrective" should have been used.

References

(1) "The Pharmacological Basis of Therapeutics," 4th Ed., edited by L.S. Goodman and A. Gilman, The Macmillan Co., New York, p. 517, 1970.

(2) Minutes of the Pulmonary-Allergy Drugs Advisory Committee, December 6 and 7, 1979, p. 5, in OTC Volume 04GTFM, Docket No. 76N-052G, Dockets Management Branch.

(3) Sims, J.A., G.A. do Pico, and C.E. Reed, "Bronchodilating Effects of Oral Theophylline-Ephedrine Combination," *Journal of Allergy and Clinical Immunology*, 62:15-21, 1978.

(4) Thorn, G.W., et al., editors, "Harrison's Principles of Internal Medicine," 8th Ed., McGraw-Hill Book Co., New York, pp. 342-343, 1977.

(5) Lecamwasam, D.S., et al., "Effect of Phenobarbitone on Hepatic Drug-Metabolizing Enzymes and Urinary D-Glutaric Acid Excretion in Man," *British Journal of Clinical Pharmacology*, 2:257-262, 1975.

(6) Landay, R.A., et al., "Effect of Phenobarbital on Theophylline Disposition," *The Journal of Allergy and Clinical Immunology*, 62:27-29, 1978.

(7) Brooks, S.M., et al., "Adverse Effects of Phenobarbital on Corticosteroid Metabolism in Patients with Bronchial Asthmas," *New England Journal of Medicine*, 286:1125-1128, 1972.

(8) "The Pharmacological Basis of Therapeutics," 4th Ed., edited by L.S. Goodman and A. Gilman, The Macmillan Co., New York, pp. 112-113, 1970.

50. One comment indicated that "lethargy," a feeling of fatigue or tiredness, should have been included with the cold symptoms listed by the Panel at 41 FR 38320. The comment claimed that caffeine included in a cold preparation not containing an antihistamine would combat the lethargy that affects a significant target population of persons with cold symptoms. The comment recommended that, because of its stimulant action, caffeine at a dosage of 15 to 30 mg should be permitted in cold preparations to overcome symptoms of lethargy.

The agency agrees that lethargy may be a symptom which accompanies a cold. In the final monograph for OTC stimulant drug products, caffeine was included as a monograph drug for the indication "helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness" in a dose of 100 to 200 mg (53 FR 6105). The comment did not submit any data to support its suggested inclusion in a cough-cold combination of 15 to 30 mg (or a higher quantity) of caffeine to combat "lethargy" accompanying the common cold. Therefore, the agency is unable to accept the comment's request at this time.

51. One comment requested Category I classification for a combination product containing phenylephrine hydrochloride (a nasal decongestant) and methapyrilene hydrochloride (an antihistamine) in a nasal spray and submitted two clinical studies in support of its request (Ref. 1).

The Panel classified combination products containing a nasal decongestant and an antihistamine administered topically in a spray or drops in Category III. The Panel specified that additional studies are necessary to assess the contribution of an antihistamine administered by the topical route because there are inadequate studies demonstrating the effectiveness of topically applied antihistamines in such combinations (41 FR 38328). In the studies submitted by the comment, nasal sprays containing 0.125 percent methapyrilene hydrochloride alone, 0.50 percent phenylephrine hydrochloride alone, and 0.125 percent methapyrilene and 0.50 percent phenylephrine in combination were studied on a double-blind, parallel (non-crossover) basis in patients with allergic rhinitis (ragweed hay fever) and acute coryzal rhinitis. The agency's evaluation of the studies indicates that methapyrilene hydrochloride alone had no significant effect on the symptomatology of coryza or allergic rhinitis, and that there were no significant differences between phenylephrine alone and the combination of phenylephrine and methapyrilene in relieving the symptoms of coryza and allergic rhinitis.

In light of the finding by the National Cancer Institute that methapyrilene is a potent carcinogen in rats and therefore a potential carcinogen in man, manufacturers have voluntarily recalled all methapyrilene-containing products from the market, and FDA has withdrawn all NDA's for products containing methapyrilene. (See the preamble to the tentative final monograph for OTC antihistamine drug products published in the **Federal Register** of January 15, 1985; 50 FR 2200.) The agency has placed all OTC methapyrilene-containing drug products in Category II for safety, and the combination of phenylephrine hydrochloride and methapyrilene hydrochloride in a nasal spray or drops for OTC use will not be considered further in this document. However, the combination of a Category I antihistamine and a Category I nasal decongestant in a nasal spray or drops will remain in Category III until substantive data are submitted to demonstrate the effectiveness of such a combination.

Reference

(1) Comment COIII, Docket Number 76N-0052, Dockets Management Branch.

52. One comment objected to the reformulation of a specific cough-cold combination drug product, contending that the reformulated product is not "as effective as the one [FDA] forced to be taken off the market."

The combination product referred to in the comment was submitted to the Panel in October 1972 and at that time contained 1 mg chlorpheniramine maleate (an antihistamine), 5 mg phenylephrine hydrochloride (a nasal decongestant), 300 mg acetaminophen (an analgesic-antipyretic), and 30 mg caffeine (a stimulant) per tablet at an adult dosage of two tablets every 4 hours (Ref. 1). The presently marketed combination contains 2 mg chlorpheniramine maleate, 18.75 mg phenylpropanolamine (a nasal decongestant), and 325 mg acetaminophen per tablet at an adult dosage of two tablets every 4 hours. The reformulation of the combination product was probably due in part to the recommendations of the Panel, but was undertaken voluntarily by the manufacturer.

The Panel recommended 4 mg of chlorpheniramine as the minimum effective adult dose (41 FR 38384), and the agency adopted this dose in the tentative final monograph for OTC antihistamine drug products (50 FR 2217). The previous combination product formulation provided an adult dose of 2 mg chlorpheniramine in two tablets, only half the Panel's recommended effective dose. The new combination provides an effective adult dose of 4 mg chlorpheniramine in two tablets.

The previous combination also provided an oral adult dose of 10 mg phenylephrine hydrochloride as a nasal decongestant in two tablets. The new combination provides an adult dose of 37.5 mg phenylpropanolamine as a nasal decongestant in two tablets. Both the dose of phenylephrine in the previous combination and the dose of phenylpropanolamine in the new combination were found by the Panel to be effective as nasal decongestants. Therefore, the change in the nasal decongestant ingredients included in the combination would not appear to be based on the Panel's recommendations. After the Panel's report was published, FDA became aware of studies indicating that certain dosages of phenylpropanolamine may cause elevation of blood pressure. For this reason, the agency has decided to address the safety of phenylpropanolamine for nasal decongestant use in a future **Federal Register** publication. Therefore, phenylpropanolamine is not categorized in the nasal decongestant tentative final monograph. (See the **Federal Register** of January 15, 1985; 50 FR 2220.)

The previous combination provided an adult dose of 60 mg caffeine in two tablets, while the new combination does not contain caffeine. The Panel recognized that caffeine may be included in cough-cold products that contain antihistamines as a "stimulant corrective" (41 FR 38417), but did not find sufficient data to support the effectiveness of caffeine for this use and placed caffeine in Category III. (The agency notes that the Panel used the terms "stimulant corrective" in referring to caffeine; however, the term "sedative corrective" should have been used. The agency hereby makes the correction.) No further data have been submitted to the agency to demonstrate the effectiveness of caffeine as a "sedative corrective." Caffeine will, therefore, remain in Category III for this use.

The previous combination provided an adult dose of 600 mg acetaminophen in two tablets, while the new combination provides an adult dose of 650 mg acetaminophen in two tablets. The Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products recommended an adult dosage range of 325 to 650 mg acetaminophen as safe and effective in the advance notice of proposed rulemaking published in the **Federal Register** of July 8, 1977 (42 FR 35346) at 42 FR 35416. That Panel's recommendations would not require a change in the formulation of the combination.

The agency disagrees with the comment's contention that agency actions have resulted in a less effective cough-cold combination drug product. The key change in the formulation of the combination, based on the recommendations of the Cough-Cold Panel and the Internal Analgesic Panel, was an increase in the dose of chlorpheniramine to an effective dose (from 2 mg to 4 mg). Further changes in dosage or ingredients may be required when the final monograph for OTC cough-cold products is published depending on the outcome of the agency's review of data on the safety of phenylpropanolamine as a nasal decongestant. However, combinations of an antihistamine, an oral nasal decongestant, and an analgesic-antipyretic ingredient have been placed in Category I in this tentative final monograph. The agency believes that its decisions, which are based on the review of data, marketing experience, and the recommendations of experts regarding the safety and effectiveness of cough-cold drug products, will result in the marketing of only those OTC cough-cold drug products that are safe and effective.

Reference

(1) OTC Volume 040027.

53. One comment pointed out that a marketed combination drug product containing belladonna alkaloids (an anticholinergic), phenylpropanolamine hydrochloride (a nasal decongestant), and chlorpheniramine maleate (an antihistamine) was similar to a combination drug product that was deemed "irrational" by the AMA Council on Drugs, 1971. The comment expressed its concern about the safety of this combination drug product because of reported cases of urinary retention, dizziness, blurring of vision, etc. The comment stated that in short-term animal studies on this combination drug product the ingredients taken in combination "potentiated" the toxic effects of the individual ingredients. The comment objected to the Panel's report for permitting marketing of this combination drug product pending study and for not recommending study for "long term" effects.

The Panel did not specifically classify the combination product mentioned by the comment, i.e., an anticholinergic, a nasal decongestant, and an antihistamine. It did, however, classify combinations containing atropine, an anticholinergic drug that is a component of belladonna alkaloids, and an oral nasal decongestant as Category III, stating that the available safety data were insufficient to make a final determination and that additional studies were necessary to assess the potential additive central nervous system stimulant side effects (41 FR 38328). Similarly, the Panel classified combinations containing an antihistamine and an anticholinergic as Category III, stating that additional studies are necessary to assess the nature and extent of additive anticholinergic side effects (41 FR 38328).

Based on the Panel's classification of these combinations (atropine with an oral nasal decongestant, and an antihistamine with an anticholinergic), the combination of an anticholinergic, an oral nasal decongestant, and an antihistamine would satisfy the criteria for Category III combination drug products. However, because there are no monograph anticholinergic ingredients at this time, all OTC combination drug products containing an anticholinergic ingredient are considered Category II (nonmonograph) conditions. (See the final rule for OTC anticholinergic drug products published in the **Federal Register** of November 8, 1985; 50 FR 46582.)

The agency has evaluated the safety of this combination drug product by considering the safety of the individual active ingredients. The Panel recognized the problem of urinary retention associated with belladonna alkaloids and recommended that an appropriate warning "Do not take this product if you have * * * difficulty in urination due to enlargement of the prostate gland except under the advice and supervision of a physician" be included in the labeling of products containing this ingredient. The agency concurred at 47 FR 30009 in the tentative final monograph for OTC anticholinergic drug products and expectorant drug products published on July 9, 1982.

Sympathomimetic drugs such as phenylpropanolamine, a nasal decongestant, may also cause urinary retention problems, and the agency has proposed the following warning for nasal decongestant drugs at 50 FR 2227 in the tentative final monograph for OTC nasal decongestant drug products: "Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor." The labeling for combination drug products will include the applicable warning statements for the individual ingredients contained in the product. The warnings may be combined where appropriate to eliminate

repetition. Therefore, warnings will be adequately provided.

The Panel recognized blurring of vision and other side effects which can occur with the use of belladonna alkaloids and recommended in § 341.70(b)(2) that the labeling for products containing anticholinergics bear a warning that consumers should stop taking this product if any of these side effects occur. However, the Panel did not include dizziness as one of the side effects identified in this section. The agency previously recognized dizziness as a possible side effect of belladonna alkaloids and added "dizziness" to the warning statement in § 341.70(c)(2) in the tentative final monograph for OTC anticholinergic drug products and expectorant drug products (47 FR 30009). Because these specific warning statements will be required in the labeling for the combination drug product should it obtain monograph status, the agency believes that the concern expressed by the comment regarding safety has been adequately addressed.

The agency concludes that animal studies for long-term toxic effects as urged by the comment are not needed based on the Panel's evaluation of belladonna alkaloids (41 FR 38378). The Panel believed that it was not necessary to recommend such studies because belladonna alkaloids have been marketed and widely used for many years.

The Panel stated that, in determining the safety of a drug or combination of drugs, it considered both animal and human studies (41 FR 38335). Although animal studies were of interest, the Panel pointed out that they were seldom very helpful because it would have been unusual for a drug to reach the market without satisfactory animal safety data. The agency is unaware of any data generated by animal studies to support the comment's contention that ingredients such as belladonna alkaloids, phenylpropanolamine hydrochloride, and chlorpheniramine maleate when taken together in a combination product produced a potentiation of toxic effects. No new data were submitted by the comment.

The combination drug product discussed by the comment has been marketed OTC since 1961 with an approved NDA for safety. In 1980, the manufacturer reformulated the product to delete the anticholinergic ingredient. Therefore, there has been no need for regulatory action prior to publication of a final rule.

As mentioned above, the agency believes that the combination of an anticholinergic, an oral nasal decongestant, and an antihistamine satisfies the criteria for Category III combination drug products. However, because at this time, there are no Category I (monograph) anticholinergic ingredients in the final rule for OTC anticholinergic drug products (published in the **Federal Register** of November 8, 1985; 50 FR 46582), all combination drug products containing an anticholinergic ingredient are Category II (nonmonograph) and may not be shipped in interstate commerce after November 10, 1986, the effective date of the final rule for OTC anticholinergic drug products. Thus, in this tentative final monograph, the combination of an anticholinergic, an oral nasal decongestant, and an antihistamine; the combination of an antihistamine and an anticholinergic; and the combination of atropine and an oral nasal decongestant are being classified in Category II because all anticholinergic ingredients are nonmonograph. If, in the future, any ingredient is determined to be generally recognized as safe and effective as an OTC anticholinergic, and if adequate data support the safety and effectiveness of a combination of an anticholinergic, an oral nasal decongestant, and an antihistamine, or any of the other combinations mentioned above, such combinations may be proposed for inclusion in the final monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products.

54. Several comments questioned the safety and effectiveness of bronchodilator drug products containing a combination of theophylline and ephedrine, and opposed the OTC availability of such combinations. The comments stated that the addition of ephedrine to theophylline results in synergistic toxicity without significant additive therapeutic effect, and that these combination products contain suboptimal dosages of theophylline. Another comment requested that a combination of a methylxanthine (theophylline) bronchodilator, a sympathomimetic (ephedrine) bronchodilator, and an expectorant be classified as Category I.

In the **Federal Register** of December 10, 1976 (41 FR 54032), the Commissioner disagreed with the Panel's recommendation to allow the use of theophylline as a single ingredient in OTC drug products and limited the use of theophylline as a single ingredient to prescription drug products. The Commissioner also advised that the use of theophylline, both as a single ingredient and in combination, in both prescription and OTC drug products, was undergoing extensive review in FDA.

In the tentative final and final monographs for OTC bronchodilator drug products, published in the **Federal Registers** of October 26, 1982 (47 FR 47520) and October 2, 1986 (51 FR 35338), respectively, the agency confirmed its earlier decision that theophylline as a single ingredient is Category II, i.e., nonmonograph, as an OTC bronchodilator. In this present document, the agency is proposing that combinations containing theophylline also be classified in Category II.

Currently marketed OTC combinations of theophylline and ephedrine usually contain theophylline (100 to 130 mg), ephedrine (24 mg), and either guaifenesin (100 mg), or phenobarbital (8 mg). Questions have been raised whether the low dose of theophylline in these combination products is therapeutically effective, and whether the addition of the ephedrine to theophylline increases the risk of central nervous system side effects without increasing the effectiveness of the product.

The agency has reviewed many studies on theophylline as a single ingredient and in combination with other ingredients. Weinberger and Bronsky (Refs. 1 and 2), Jenne (Ref. 3), and Piafsky and Ogilvie (Ref. 4) recommended dosage titration with serum level control to insure a safe and effective dose because of the wide individual response to orally administered theophylline. Piafsky and Ogilvie commented that effectiveness and toxicity are better correlated with plasma theophylline concentrations than with dosage. Frequently, toxic effects associated with elevated serum levels of theophylline are not preceded by minor adverse effects (Refs. 5, 6, and 7).

Sims et al. (Ref. 8) and Tinkelman and Avner (Ref. 9) reported evidence of an additive effect of the theophylline and ephedrine combination. Sims et al. reported that a single dose of the combination of ephedrine (25 mg) and theophylline (130 mg) produced a bronchodilator effect in patients with mild to moderate asthma, that the combination was more effective than either drug alone, and that the combination tended to cause slightly more side effects (tremor, nervousness, nausea), but found that these differences were not striking. The authors noted that, although a low dose of theophylline and a low dose of ephedrine produced a greater improvement, this result did not preclude the possibility that similar improvement could have been achieved with a larger dose of theophylline alone.

Tinkelman and Avner reported that ephedrine enhanced bronchodilation when added to the treatment of theophylline-titrated children, but noted that the improvement was not overwhelming. In addition, they reported that the prolonged administration of ephedrine did not cause either tolerance or toxicity during an 8-week study. Although no significant increase in adverse effects was observed, it should be noted that in this study, the ephedrine dose was independently administered and 40 percent less than if administered in fixed combination.

Riegelman et al. (Ref. 10) designed a study to determine whether plasma levels of theophylline in the range of 12 to 18 micrograms per milliliter (μ/mL) (i.e, plasma levels comparable to a high dose of theophylline) are necessary to obtain a satisfactory therapeutic effect, or whether a satisfactory therapeutic effect is obtained at a lower plasma theophylline range of 4 to 8 μ/mL (i.e., plasma levels comparable to a low dose of theophylline). The study was also designed to determine whether a beneficial additive effect is demonstrated with a combination of ephedrine, phenobarbital, and theophylline at a low dose (i.e., plasma concentration of theophylline of 4 to 8 μ/mL). In the study, plasma theophylline levels for each patient were calculated, and the exact amount of theophylline required to achieve low and high dose concentrations for each patient was determined. The results indicated that ephedrine has no beneficial additive effect in combination with theophylline, but that theophylline given at a low dose was associated with subjective and objective superiority (over no therapy) in 27 of the 28 patients that were studied. It should be noted that the range of dosage required to achieve the low plasma concentration was extremely wide and associated with only a variable degree of success in attaining the desired level. Accordingly, the study demonstrates the need for individual titration of theophylline.

On July 20 and 21, 1981, the FDA Pulmonary-Allergy Drugs Advisory Committee met to discuss the completed Riegelman study and the status of theophylline and ephedrine combination drug products. The Committee agreed that there is a lack of clinically documented evidence of an additive effect with the theophylline and ephedrine combination drug product (Ref. 11). On November 4, 1982, the Committee continued its discussion of theophylline and ephedrine combination drug products, reporting that there is a lack of adequate evidence of an additive or synergistic effect of theophylline and ephedrine in combination, that the combination of the two ingredients does not permit using a lower dosage of either ingredient to produce bronchodilation, that there is an increase in incidence of side effects from use of the combinations, and that it did not favor the continued OTC or prescription marketing of theophylline and ephedrine fixed combination drug products (Ref. 12).

Disadvantages of theophylline and ephedrine combination products have been reported by Weinberger and Bronsky (Refs. 1 and 2), who stated that there was no significant clinical benefit from using the combination product. They reported that ephedrine in combination with theophylline appeared to add little benefit to that of theophylline when the latter is provided in a dosage titrated for the individual patient. Moreover, the studies indicated that ephedrine increased the frequency of such side effects as insomnia, nervousness, and gastrointestinal complaints, suggesting toxicity. Jenne (Ref. 3) commented that theophylline and ephedrine combinations provide one-fourth to one-half the optimum dose of theophylline and less bronchodilation than the full theophylline regimen. Piafsky and Ogilvie (Ref. 4) reported that the use of the combination is not warranted because the theophylline dose should be individualized. They added that when theophylline therapy is unsatisfactory, other oral medications such as ephedrine may be added, but only small increases in efficacy and some increase in toxicity should be expected. Plummer (Ref. 5) noted the importance of monitoring serum theophylline levels and the inadequacy of the dose of theophylline in these combination drug products. Webb-Johnson and Andrews (Ref. 13) commented that ephedrine often produces side effects, and tolerance to its action develops. Rachelefsky et al. (Ref. 14) studied a sustained-release theophylline preparation (260 mg administered every 12 hours) and ephedrine (30 mg) and found that ephedrine did not add significantly to improvement in pulmonary function, nor did it influence serum theophylline levels.

Other investigators have studied theophylline in combination with other ingredients. Deutsch et al. (Ref. 15), demonstrated that a low dose of oral theophylline (130 mg) failed to produce acute bronchodilatation or to produce additive bronchodilatation when combined with terbutaline (2.5 mg), a potent long-acting beta-2 adrenergic stimulant used in the treatment of asthma. Cohen (Ref. 16) compared terbutaline tablets to a sustained-release combination tablet containing theophylline, ephedrine, and phenobarbital and concluded that, although terbutaline was effective, the combination of theophylline, ephedrine, and phenobarbital produced greater bronchodilation. Lyons et al. (Ref. 17) commented on the Weinberger and Bronsky data (Ref. 1), stating that mild-to-moderate asthmatics (as opposed to severe and chronic asthmatics) may benefit from the conventional doses found in theophylline and ephedrine combinations.

Piafsky and Ogilvie (Ref. 4) reported that phenobarbital added to a theophylline and ephedrine combination in the doses commonly used in these combination products does not effectively counteract the central nervous system effect of theophylline. Webb-Johnson and Andrews (Ref. 13) and Plummer (Ref. 5) reported that theophylline, ephedrine, and phenobarbital combinations should not be used because phenobarbital may cause respiratory depression, particularly if the patient is suffering from hypoxemia (deficient oxygen in the blood) and hypercarbia (excess carbon dioxide in the blood). As discussed in comment 49 above, combinations containing theophylline, ephedrine, and phenobarbital have been classified as Category II.

The agency believes there is insufficient evidence to support the use of theophylline and ephedrine combinations. Although several investigators (Refs. 8, 9, and 16) have found theophylline and ephedrine combinations to be beneficial, in one study ephedrine was added to the treatment of theophylline-titrated children (Ref. 9); in another study, although the theophylline dose was low, it was only a single dose study and, as noted by the investigator, did not preclude the possibility of similar improvement with a higher dose of theophylline given alone (Ref. 8); and in the third study, phenobarbital was included in the combination (Ref. 16).

The data that have been reviewed indicate that ephedrine adds little benefit to the theophylline and ephedrine combination when the theophylline is provided in a dosage that is titrated for the individual patient (Refs. 1 through 5). Additionally, a number of investigators have pointed out the need for individual titration of theophylline (Refs. 1 through 4, and 10). An increase in adverse effects has also

been associated with the use of theophylline and ephedrine combination drug products (Refs. 1, 2, 5, and 12). For several years, the agency has been reviewing the use of theophylline in both prescription and OTC drugs. In a Drug Efficacy Study Implementation (DESI) notice and Notice of Opportunity for Hearing (see the **Federal Register** of February 29, 1984; 49 FR 7454), the agency discussed the safety and effectiveness of certain combination drug products containing xanthine derivatives. FDA discussed new information in that notice and concluded that there is a lack of substantial evidence that each ingredient of the theophylline and ephedrine combination drug product makes a contribution to the claimed effects of the product. Moreover, as the Commissioner stated in the **Federal Register** of December 10, 1976 (41 FR 54032), careful titration based on measurement of theophylline serum levels is necessary. In the bronchodilator tentative final monograph (47 FR 47520), the agency reaffirmed its position that theophylline should be Category II and should not be available OTC as a single ingredient product because it is essential that a physician titrate theophylline dosage, based on individual patient measurements of theophylline serum levels. The agency believes that dosage titration is necessary whether theophylline is administered as a single ingredient or in combination with another drug. Therefore, the agency concludes that theophylline should be administered under professional supervision and is classifying any combination drug product containing theophylline as Category II in this tentative final monograph.

References

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(2) Weinberger, M., and E. Bronsky, "Interaction of Ephedrine and Theophylline," *Clinical Pharmacology and Therapeutics*, 17:585–592, 1975.

(3) Jenne, J.W., "The Clinical Pharmacology of Bronchodilators," *Basics of RD*, 6:18–23, 1977

(4) Piafsky, K.M., and R.I. Ogilvie "Dosage of Theophylline in Bronchial Asthma," *The New England Journal of Medicine*, 292:1218–1221, 1975.

(5) Plummer, A.L., "Choosing a Drug Regimen for Obstructive Pulmonary Disease—1 Agents to Achieve Bronchodilatation," *Postgraduate Medicine*, 63:36-48, 1978.

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(9) Tinkelman, D.G., and S.E. Avner, "Ephedrine Therapy in Asthmatic Children," *Journal of the American Medical Association*, 237:553–557, 1977.

(10) Riegelman, S., et al., "Assessment of Theophylline Bronchodilator Activity," draft of unpublished data, 1981, in OTC Volume 04GTFM.

(11) Minutes of the FDA Pulmonary-Allergy Advisory Committee Meeting, July 20–21, 1981, in OTC Volume 04GTFM.

(12) Minutes of the FDA Pulmonary-Allergy Advisory Committee Meeting, November 4, 1982, in OTC Volume 04GTFM.

(13) Webb-Johnson, D.C., and J.L. Andrews, "Bronchodilator Therapy (Second of Two Parts)," *The New England Journal of Medicine*, 297:758–764, 1977.

(14) Rachelefsky, G.S., et al., "A Sustained Release Theophylline Preparation," *Annals of Allergy*, 40:252–257, 1978.

(15) Deutsch, R.I., et al., "Bronchodilator Effects of Low Doses of Oral Theophylline and Terbutaline in Asthmatic Subjects," *Annals of Allergy*, 45:137–143, 1980.

(16) Cohen, B.M., "The Cardiorespiratory Effects of Oral Terbutaline and an Ephedrine-Theophylline-Phenobarbital Combination: Comparison in Patients with Chronic Obstructive Ventilatory Disorders," *Annals of Allergy*, 40:233–239, 1978.

(17) Lyons, H.A., et al., "Theophylline and Ephedrine in Asthma," *Current Therapeutic Research*, 18:573–577, 1975.

55. One comment (Ref. 1) submitted new data from three controlled clinical studies on the combination of 1-desoxyephedrine and aromatics (camphor (54 mg), menthol (80 mg), methyl salicylate (11 mg), bornyl acetate (0.2 mg), and lavender oil (4 mg)) used as a topical nasal decongestant (administered by a nasal inhaler) (Refs. 2, 3, and 4). The comment requested Category I status for the combination based on these data, some of the data reviewed by the Panel (Refs. 5 and 6), and the manufacturer's marketing experience.

On the basis of the above data (Refs. 2 through 6) and an additional study (Ref. 7), the agency proposed Category I status for 1-desoxyephedrine as a single-ingredient topical nasal decongestant in the tentative final monograph for OTC nasal decongestant drug products (50 FR 2225). Four of these same studies also support the Category I classification of 1-desoxyephedrine combined with aromatics by showing that the combination of 1-desoxyephedrine and aromatics is superior to placebo, aromatics alone, and 1-desoxyephedrine alone (Refs. 2 through 6). The aromatic mixture when tested alone had little effect. The combination of 1-desoxyephedrine and the aromatic mixture did not cause rebound nasal congestion when inhaled every 2 hours six times daily for a 7-day period (Ref. 4).

Based on the data reviewed, the agency proposes to classify the 150 mg aromatic mixture in combination with 50 mg of 1-desoxyephedrine as a Category I topical nasal decongestant combination to be administered by a nasal inhaler. The agency is unaware of a marketed product containing the aromatic mixture alone and proposes to classify the aromatic mixture alone in Category II. This approach is consistent with paragraph 5 of the agency's "General Guidelines for OTC Drug Combination Products, September 1978" (cited above), which provides that "in some cases an ingredient may be appropriate for use only in a specific combination or data may be available only to support the use of the ingredient in combination but not as a single ingredient. In such cases the ingredient will be placed in Category I for use only in permissible combinations and not as a single ingredient." The studies indicate that the aromatic mixture enhances the effectiveness of the 1-desoxyephedrine.

The proposed adult dosage of the combination is two inhalations in each nostril not more often than every 2 hours from an inhaler that delivers in each 800 mL of air 0.04 to 0.15 mg of 1-desoxyephedrine. In keeping with the guidelines established by the Panel (41 FR 38333), the dosage for children 6 to under 12 years of age is one-half of the adult dosage. (See 41 FR 38328, paragraph C.10.i.). Because the results of one study showed that rebound congestion did not occur in 52 subjects who inhaled the combination of 50 mg of 1-desoxyephedrine and 150 mg of aromatic ingredients from an inhaler every 2 hours six times daily for a 7-day period (Ref. 4), the agency is proposing in this tentative final monograph that the use of the combination of 1-desoxyephedrine and aromatics as a topical nasal decongestant be limited to not more than 7 days instead of the 3-day limit for other topical nasal decongestants that cause rebound congestion.

The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Refs. 8 and 9).

References

(1) Comment Nos. COIII, CR0003, and SUP015, Docket No. 76N–0052, Dockets Management Branch.

(2) Connell, J. T., "Inhaler," (Study CRD 74-30), draft of unpublished study in Comment No. CO111, Docket No. 76N-0052, Dockets Management Branch.

(3) Connell, J. T., "Inhaler," (Study CRD 74-58), draft of unpublished study in Comment No. CO111 (Volume 4), Docket No. 76N-0052, Dockets Management Branch.

(4) Connell, J. T., "Nasomucosal Rebound Delta-P," (Study CRD 75-45), draft of unpublished study in Comment No. CO111, Docket No. 76N-0052, Dockets Management Branch.

(5) Turgeon, R. F., "Vick Inhaler," (Study CRD 70-24), draft of unpublished study in OTC Volume 040298.

(6) Memo to W. E. Burke, from E. B. Cohen, "Vick Inhaler: Vick Rhinorheometer Study—Maine Research" (supersedes Study CRD 70-24, dated February 11, 1971), in OTC Volume 040298.

(7) Connell, J. T., "Nasal Decongestant Delta-'P' Method," (Study CRD 74-10A), draft of unpublished study in Comment No. CO111, Docket No. 76N-0052, Dockets Management Branch.

(8) Letter from W. E. Gilbertson, FDA, to G. F. Hoffnagle, Richardson-Vicks Inc., coded LET072, Docket No. 76N-052N, Dockets Management Branch.

(9) Letter from W. E. Gilbertson, FDA, to G. F. Hoffnagle, Richardson-Vicks, Inc., coded LET080, Docket No. 76N-052N, Dockets Management Branch.

56. One comment submitted data to support the reclassification of a combination of volatile substances, i.e, menthol, camphor, eucalyptus oil, thymol, oil of turpentine, cedarleaf oil, and myristica oil, in a petrolatum ointment from Category III to Category I as an antitussive for topical application to the chest. The data included statistical reevaluations of four citric acid aerosol induced cough studies reviewed by the Panel (Refs. 1, 2, and 3) (these statistical reevaluations were not available to the Panel for review), one study in chronic bronchitis that was originally reviewed by the Panel (Ref. 4), and one new study in patients with chronic cough (Ref. 5).

Four of the studies show that the combination of menthol, camphor, eucalyptus oil, thymol, oil of turpentine, cedarleaf oil, and myristica oil applied to the chest as an ointment in a petrolatum base is more effective in reducing coughs than each individual ingredient in the combination when tested separately (Refs. 1, 3, and 4). The antitussive effect lasted for up to 2.5 hours. The data provide no evidence that the individual ingredients thymol, oil of turpentine, cedarleaf oil, or myristica oil have a statistical advantage over the petrolatum control. Study CRD 74-19/B supports the effectiveness of 1.3 percent eucalyptus oil (Ref. 1), and study CRD 74-64 shows that 1.3 percent eucalyptus oil tended to produce a lower cough count than did the petrolatum control (Ref. 4). Study CRD 75-40 provides evidence that the combination of 2.6 percent menthol, 4.7 percent camphor, and 1.2 percent eucalyptus oil in a petrolatum base is more effective in reducing coughs than a combination of 0.38 percent cedarleaf oil, 0.485 percent myristica oil, 0.076 percent thymol, and 4.5 percent oil of turpentine in a petrolatum base (Ref. 2). At various time points, the combination of menthol, camphor, eucalyptus oil, thymol, oil of turpentine, cedarleaf oil, and myristica oil in a petrolatum base was more effective in reducing the number of coughs as compared to the other formulations. All formulations were more effective than the petrolatum alone.

Based on the data, the agency concludes that there is sufficient evidence to place the combination of menthol, camphor, and eucalyptus oil in a suitable ointment vehicle in Category I as an antitussive. Concentrations of 4.7 to 5.3 percent camphor and 2.6 to 2.8 percent menthol, as single antitussive ingredients, have previously been proposed for Category I for use in a suitable ointment vehicle (48 FR 48594). Eucalyptus oil as a single ingredient currently remains in Category III as an antitussive drug (48 FR 48583). While studies CRD 74-19/B and 74-64 are not sufficient to reclassify eucalyptus oil in Category I, the studies do indicate that eucalyptus oil makes a contribution to the effectiveness of the combination product. The Panel concluded that study CRD 74-19/B is supportive but does not provide sufficient evidence of the claimed antitussive effectiveness of eucalyptus oil as a single active ingredient in an ointment.

Thymol (0.1 percent) and oil of turpentine (4 percent) were reviewed by the Panel and placed in Category III as antitussives because additional effectiveness data were needed. The data that have been reviewed thus far by the agency do not show that thymol and oil of turpentine are effective antitussives, nor do the data adequately show the contribution of thymol and oil of turpentine to the effectiveness of the combination product. Based on the concentrations of these ingredients in the product, the agency considers thymol to be an inactive ingredient; however, the oil of turpentine would not be considered an inactive ingredient. Although cedarleaf oil and myristica oil were tested, the agency also considers these ingredients to be inactive ingredients.

Although this combination product contains more than two antitussive active ingredients from the same pharmacologic group (i.e., menthol, camphor, and eucalyptus oil), paragraph 3 of the agency's "General Guidelines for OTC Drug Combination Products" (cited above) permits such a combination " * * * if the combination offers some advantage over the active ingredients used alone, and the combination is, on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose." Eucalyptus oil may be included in the combination based on paragraph 5 of the agency's "General Guidelines," which states that "in some cases an ingredient may be appropriate for use only in a specific combination or data may be available only to support the use of the ingredient in combination but not as a single ingredient. In such cases the ingredient will be placed in Category I for use only in permissible combinations and not as a single ingredient."

Based on the above guidelines, the agency proposes that the combination containing menthol (2.6 to 2.8 percent), camphor (4.7 to 5.3), and eucalyptus oil (1.2 to 1.3 percent) in a suitable ointment vehicle be classified as a Category I topical antitussive combination drug product.

The labeling that is proposed for menthol and camphor in § 341.74 of the final monograph for antitussive drug products will also be proposed for the combination of menthol, camphor, and eucalyptus oil. (See 52 FR 30055.)

The agency's detailed comments on the data are on file in the Dockets Management Branch (Ref. 6).

References

(1) Cash, W., and K. Martin, "Recalculation of Significance Levels (P-values) for the VapoRub CAA Studies CRD No. 74-19/A and 74-19/B—Dr. Packman," in Comment No. CR0004, Docket No. 76N-0052, Dockets Management Branch.

(2) Cash, W., and K. Martin, "Recalculation of Significance Levels (P-values) for the VapoRub CAA Study CRD No. 75-40—Dr. Packman," in Comment No. CR0004, Docket No. 76N-0052, Dockets Management Branch.

(3) Cash, W., and K. Martin, "Recalculation of Significance Levels (P-values) for the VapoRub CAA Study CRD No. 74-52-Dr. Packman," in Comment No. CR0004, Docket No. 76N-0052, Dockets Management Branch.

(4) Dennis, S.R.K., et al., "A Study for the Measurement of the Antitussive Effects of Vicks VapoRub Compared to Eucalyptus Oil and Compared to Placebo in Stabilized Patients with Chronic Cough," (Study CRD 74-64), draft of unpublished study in OTC Volume 040060A, Docket No. 76N-0052, Dockets Management Branch.

(5) Dennis, S.R.K., P. Bass, and G. doPico, "VapoRub," (Study CRD 76-41), draft of unpublished study in Comment No. SUP008, Docket No. 76N-0052, Dockets Management Branch.

(6) Letter from W.E. Gilbertson, FDA, to G.F. Hoffnagle, Richardson-Vicks, Inc., coded LET079, Docket No. 76N-052G, Dockets Management Branch.

57. Two comments requested reclassification of a combination of eucalyptus oil and menthol from Category III to Category I as an antitussive in lozenge form. One comment contended that the written submissions and oral presentations to the Panel included adequate data to support a Category I classification of lozenge products containing this combination for antitussive use. The other comment submitted data from additional studies to show the effectiveness of a combination of not less than 5 mg eucalyptus oil and menthol for topical use as an antitussive in lozenge form.

In the final monograph for OTC antitussive drug products (52 FR 30055), menthol (5 to 10 mg) as a single ingredient has been classified as a monograph condition when used in a lozenge or compressed tablet dosage form, and eucalyptus oil as a single ingredient in a lozenge dosage form has been classified as a nonmonograph condition.

The agency has reviewed the data submitted to the Panel and concurs with its conclusion that a combination of eucalyptus oil and menthol for topical use as an antitussive in lozenge form is appropriately classified in Category III.

The agency has also reviewed the additional data and concludes that they are insufficient to support the reclassification from Category III to Category I of a combination of menthol and not less than 5 mg eucalyptus oil for topical use in lozenge form. In two studies (Refs. 1 and 2), the following were compared to a control lozenge containing only the candy base and to a lactose capsule placebo: A 9.3 mg menthol lozenge (study CRD 77-58) and a combination product containing 5.27 mg menthol and 0.6 mg eucalyptus oil (CRD 78-19). Although the studies indicate the antitussive effectiveness of the lozenges, the data are not supportive of eucalyptus oil because no comparisons to eucalyptus oil as a single ingredient were made.

Study CRD 76-49R, a single-blind crossover study, was conducted in subjects with artificially induced cough to compare the antitussive effectiveness of a combination product containing 8.8 mg menthol and 6 mg eucalyptus oil, with 9.8 mg menthol alone, 5.7 mg eucalyptus oil alone, and a vehicle control, all in a lozenge dosage form. Although this study is supportive of the effectiveness of eucalyptus oil as an antitussive, the agency did not find any evidence that eucalyptus oil contributes to the effectiveness of the combination lozenge. The menthol lozenge produced numerically greater reductions in cough counts at all three challenge times and overall ($P < .05$) than did the combination lozenge (Ref. 3).

Study CRD 75-26, a single-blind crossover study, was conducted in patients with chronic cough due to bronchopulmonary disease to compare the antitussive effectiveness of a combination product containing 7.5 mg menthol and 5.4 mg eucalyptus oil with a 7.5 mg menthol lozenge, a 5.1 mg eucalyptus oil lozenge, and a control lozenge. There were no significant differences among these four treatments in reducing cough counts. Thus, this study does not demonstrate that eucalyptus oil contributes to the antitussive effectiveness of menthol in a combination product (Ref. 4).

Study CRD 76-43, a single-blind parallel study, was conducted in patients with chronic cough due to bronchopulmonary disease to compare the antitussive effectiveness of a combination product containing menthol and eucalyptus oil, a menthol lozenge, a eucalyptus oil lozenge, and a control lozenge (Ref. 5). A significant reduction in overall cough counts was reported for these four treatments ($P < .05$). However, comparisons of pairs of tested lozenges did not show any significance; for example, menthol compared to the combination product or the control compared to the combination product. The agency concludes that, in addition to the lack of difference shown between eucalyptus oil and the control, the results obtained with the combination lozenge were virtually the same as those obtained with the menthol lozenge.

The agency concludes that the data from studies CRD 76-49R, CRD 75-26, and CRD 76-43 do not demonstrate that eucalyptus oil contributed to the antitussive effectiveness of the combination lozenge because the combination lozenge did not reduce cough counts in subjects more significantly than did the menthol lozenge alone. Therefore, the agency proposes to classify the combination of menthol and eucalyptus oil in a lozenge form as Category III in this tentative final monograph.

The agency's detailed comments and evaluations on the data are on file in the Dockets Management Branch (Refs. 6 and 7).

References

(1) Finkel, S., and S. Zuckerman, "Victors," (Study CRD 77-58), draft of unpublished study in Comment No. SUP009, Docket No. 76N-0052, Dockets Management Branch.

(2) Finkel, S., and S. Zuckerman, "Vicks Medicated Cough Drops," (Study CRD 78-19), draft of unpublished study in Comment No. SUP009, Docket No. 76N-0052, Dockets Management Branch.

(3) Packman, E.W., "Victors Cough Drops," (Study CRD 76-49R), draft of unpublished study in Comment No. SUP009, Docket No. 76N-0052, Dockets Management Branch.

(4) Dennis, S.R.K., P. Bass, and G. doPico, "Victors Squares," (Study CRD 75-26), draft of unpublished study in Comment No. SUP009, Docket No. 76N-0052, Dockets Management Branch.

(5) Dennis, S.R.K., P. Bass, and G. doPico, "Victors," (Study CRD 76-43), draft of unpublished study in Comment No. SUP009, Docket No. 76N-0052, Dockets Management Branch.

(6) Letter from W.E. Gilbertson, FDA, to G.F. Hoffnagle, Vicks Health Care Division of Richardson-Merrell, Inc., coded ANS 81/01/29 to SUP009, Docket No. 76N-0052, Dockets Management Branch.

(7) Letter from W.E. Gilbertson, FDA, to G.F. Hoffnagle, Richardson-Vicks Inc., coded LET080, Docket No. 76N-052G, Dockets Management Branch.

58. One comment requested that a combination of menthol, camphor, eucalyptus oil, tincture of benzoin, and polyoxyethylene dodecanol (wetting agent) be classified in Category I for use as an antitussive in a steam vaporizer. The comment stated that the Panel reviewed studies on this combination drug product and indicated that the studies show a statistically significant reduction in cough counts compared to steam alone, even beyond the duration of exposure to the vapors (41 FR 38350). However, because the Panel was concerned only with individual drugs, the comment assumed that the Panel felt it inappropriate to place this combination in Category I. The comment added that the combination of menthol, camphor, eucalyptus oil, tincture of benzoin, and polyoxyethylene dodecanol should be in Category I because the safety of the product is not in question and because the route of administration (inhalation of vapors) and the ratio of ingredients is the same for this combination product as for the antitussive combination of menthol, camphor, and eucalyptus oil in an ointment that the agency has classified in Category I. In support of the effectiveness of this combination drug product, the comment cited and summarized a number of studies that were reviewed by the Panel (Ref. 1).

The agency has reviewed the data and concludes that they are insufficient to support a Category I classification of menthol, camphor, eucalyptus oil, tincture of benzoin, and polyoxyethylene dodecanol as antitussives in a steam vaporizer.

The data consist of three citric acid aerosol induced cough studies and eleven active disease state studies (Refs. 2 through 15).

The citric acid aerosol studies had the same objective and design. Each study involved 24 normal volunteers who were divided equally into three groups and given two treatment regimens (medicated and non-medicated steam) in cross-over fashion. The objective was to evaluate the efficacy of the combination drug product in reducing the frequency of cough induced by citric acid aerosol challenge. The results of the citric acid aerosol induced cough studies (CRD 68–49, CRD 72–26, and CRD 71–32) are equivocal (Refs. 2, 3, and 4). The sponsor's own conclusions indicate that only in study CRD 68–49 (phase two) was there any difference between medicated and unmedicated steam. Additionally, the number of coughs recorded after exposure to unmedicated steam was greater than the number reported at baseline, prompting the sponsor's comment that the differences between treatments "may be attributable to position bias because the 1 hour runs were done first." The results of study CRD 72–26 indicate that both treatments (medicated and unmedicated) were effective, but when compared to each other, the differences (favoring medicated steam) were only apparent at the 30 minute evaluation point. The sponsor's statement that the differences between treatments was only apparent at the 30 minute challenge time needs clarification because only Group I subjects (8 subjects) were challenged at that time. In study CRD 71–37, the sponsor states that there were no differences between regimens at any observation point and both treatments appeared effective. However, the sponsor's statistician notes that the overall values (3 way analysis of variance) favor unmedicated steam primarily due to its superiority at 4½ hours.

The agency does not consider the disease state studies adequate to demonstrate the effectiveness of the combination of ingredients contained in the product (Refs. 5 through 15). Objective cough counting was not employed in any of the studies. Study CRD 71–51 was the only study in which superiority of medicated over nonmedicated steam was reported to exist. There were no accompanying data for analysis to confirm this claim and the study design requires a comparison of values which were not included with the submitted material. In the published Larkin study, it was reported that treatment with medicated steam and polyoxyethylene dodecanol resulted in fewer coughs; however, the study was uncontrolled and subjective (Ref. 6). In the other studies, no differences in cough reduction were observed.

In reference to the Panel's statement on page 38350 of its report that two of the citric acid aerosol challenge studies provided statistically significant reductions in cough counts compared to steam alone, even beyond the duration of exposure to the vapors, the agency has found that the Panel's statement is inconsistent with the results of those studies. The agency also notes that although the combination drug product contains menthol, camphor, eucalyptus oil, tincture of benzoin, and polyoxyethylene dodecanol, and although the combination of menthol, camphor, and eucalyptus oil in an ointment as an antitussive has been proposed for Category I, tincture of benzoin and polyoxyethylene dodecanol have not been individually tested. Thus, the submitted studies cannot be used in support of the effectiveness of the combination of menthol, camphor, eucalyptus oil, tincture of benzoin, and polyoxyethylene dodecanol. The data generated from the studies using menthol, camphor, and eucalyptus oil as antitussives in an ointment also cannot be used as support for the effectiveness of the combination of menthol, camphor, and eucalyptus oil as antitussives in a steam vaporizer because the superiority of steam with aromatics over unmedicated steam has not been established. When aromatics are added to water in a vaporizer which generates steam, the superiority of medicated steam over unmedicated steam requires substantiation.

Camphor and menthol individually are monograph drugs for steam inhalation use for antitussive claims (see the **Federal Register** of August 12, 1987 (52 FR 30042)). Therefore, further effectiveness data are not needed for these ingredients. In order for the combination of camphor and menthol to be placed in Category I, data are needed that establish that the combination has some advantage over the single ingredients (see comment 37 above). If other active ingredients, such as eucalyptus oil, tincture of benzoin, or polyoxyethylene dodecanol are included, any additional ingredient must be tested alone versus placebo (steam) to demonstrate a therapeutic effect, and the entire combination must be tested versus unmedicated steam. The agency recognizes that steam is not a placebo since it has a recognized benefit, but for the proposed type of product formulation, there is no known suitable control; thus, steam appears to be the only viable alternative. The Panel classified tincture of benzoin as a Category III expectorant (as a steam inhalant). If tincture of benzoin is to be considered as an expectorant in the product, the objective measurements of sputum volume and sputum viscosity should be done and correlated with subjective evaluations. Polyoxyethylene dodecanol, a surfactant, is listed as an active ingredient in the labeling of the combination product. If this ingredient is intended as active, its enhancing of the effect of steam in reducing coughs, as claimed in the comment's submission, must be demonstrated. For a combination product containing menthol, camphor, and eucalyptus oil as antitussives, and tincture of benzoin as an expectorant, objective cough counting, sputum volume, and viscosity measurements should be performed. The studies should be conducted in patients with cough due to respiratory disease.

The agency also notes that ingredients that might indirectly relieve cough (and for which there may be no measurable antitussive activity) may actually have other pharmacologic effects such as expectorant or nasal decongestant action. In the Litchfield study (Ref. 14), there was improvement in relief of symptoms of nasal congestion with medicated steam and no differences were found for coughs. The Panel provided for a Category III classification of combination products containing several claimed active ingredients which are mixtures of volatile substances with overlapping pharmacologic activities for which a minimum effective dosage cannot be established for one or more of the ingredients when tested alone. The Panel recommended a testing procedure for such combinations and suggested that the drug effect should demonstrate a 10 percent or greater difference from placebo (41 FR 38328).

In conclusion, the data on the combination of menthol, camphor, eucalyptus oil, tincture of benzoin, and polyoxyethylene dodecanol as antitussives for use in a steam vaporizer remain inadequate and, therefore, this combination is classified in Category III for this use.

The agency's detailed comments and evaluations on the data are on file in the Dockets Management Branch (Ref. 16).

References

(1) Comment No. LET085, Docket No. 76N–052G, Dockets Management Branch.

(2) Packman, E.W., "Vaposteam," (Study CRD 68–49), draft of unpublished data, OTC Volume 040266, Dockets Management Branch.

(3) Packman, E.W., "Vaposteam," (Study CRD 72-26), draft of unpublished data, OTC Volume 040266, Dockets Management Branch.
(4) Packman, E.W., "Vaposteam," (Study CRD 71-37), draft of unpublished data, OTC Volume 040266, Dockets Management Branch.
(5) Carter, V.H., "Vaposteam," (Study CRD 71-51), draft of unpublished data, OTC Volume 040267, Dockets Management Branch.
(6) Larkin, V.D., "Polyoxyethylene Dodecanol Vaporization in the Treatment of Respiratory Infections of Infants and Children," *New York State Journal of Medicine*, 57:2667-2672, 1957.
(7) Larkin, V.D., "Broad Clinical," draft of unpublished data, OTC Volume 040267, Dockets Management Branch.
(8) Amler, A.B., "Broad Clinical," draft of unpublished data, OTC Volume 040267, Dockets Management Branch.
(9) Mund, A., "Broad Clinical," draft of unpublished data, OTC Volume 040267, Dockets Management Branch.
(10) Goodall, R.E., "Broad Clinical," draft of unpublished data, OTC Volume 040267, Dockets Management Branch.
(11) Berman, M., "Broad Clinical," draft of unpublished data, OTC Volume 040267, Dockets Management Branch.
(12) Singer, A., "Broad Clinical," draft of unpublished data, OTC Volume 040267, Dockets Management Branch.
(13) Williams, H.J., "Broad Clinical," draft of unpublished data, OTC Volume 040267, Dockets Management Branch.
(14) Litchfield, H.R., "Vaposteam, (Commercial Product)," draft of unpublished data, OTC Volume 040267, Dockets Management Branch.
(15) Ghadimi, H., "Vaposteam," (Study CRD 70-34), draft of unpublished data, OTC Volume 040267, Dockets Management Branch.
(16) Letter from W.E. Gilbertson, FDA to G.F. Hoffnagle, Richardson-Vicks, Inc., coded ANS, Docket No. 76N-052G, Dockets Management Branch.

59. One comment stated that a combination of volatile aromatic oils, i.e., menthol, camphor, eucalyptus oil, thymol, cedar leaf oil, and nutmeg oil have been historically combined in a number of products for the relief of symptoms of the common cold and have gained consumer acceptance (Ref. 1). The comment considered this combination of volatile oils as a single active ingredient rather than as a list of aromatics as single drug entities. The comment stated that well-controlled studies supporting the nasal decongestant effectiveness of the mixture of aromatics and a study on the individual aromatics are contained in the OTC volumes that were submitted to the Panel. The comment added that these studies are in keeping with the Panel's criterion that such products are mixtures of volatile substances with overlapping pharmacologic activities for which a minimum effective dosage cannot be established for one or more of the ingredients when tested alone (41 FR 38328). The comment urged FDA to consider such combinations of aromatic oils a special situation with regard to drug combinations.

The agency has reviewed the information cited by the comment and notes that the Panel specifically addressed the studies on combinations of aromatic oils as nasal decongestants referred to by the comment. The Panel pointed out that varying degrees of decongestion were noted with use of the combination product but that there were no well-controlled studies conducted on the individual ingredients to demonstrate their effectiveness as nasal decongestants (41 FR 38406-38414). Therefore, the Panel placed these ingredients in Category III. The Panel also reviewed a draft of an unpublished study by T. C. Grubb, entitled "The Nasal Decongestant Effect of Aromatic Substances" (41 FR 38407-38409). In this study, which was not placebo-controlled or double-blinded, a number of aromatic ingredients were individually tested. The ingredients were inhaled from an apparatus containing a cotton wick that was impregnated with the aromatic substance. The test was not conducted in the same manner that the product would actually be used. The Panel did not, nor does the agency, consider this study adequate to demonstrate the nasal decongestant effect of the individual aromatic ingredients. The comment did not submit any new data to support the nasal decongestant effectiveness of the individual ingredients or the combination product.

The Panel proposed a Category III classification for combination drug products containing several claimed active ingredients which are mixtures of volatile substances with overlapping pharmacologic activities for which a minimum effective dosage cannot be established for one or more of the ingredients when tested alone (41 FR 38328). The agency does not believe that the entire combination of aromatic ingredients in an ointment or steam vaporizer formulation should be considered to be this type of combination. The "antitussive" effectiveness of a combination of menthol, camphor, eucalyptus oil, thymol, oil of turpentine, cedar leaf oil, and myristica (nutmeg) oil is discussed in this document (see comment 56 above). The combination of menthol, camphor, and eucalyptus oil in a suitable ointment vehicle is proposed as a Category I combination for use as a topical antitussive. Thymol, cedarleaf oil, and myristica oil were considered inactive ingredients, based on their concentrations in the combination product; however, oil of turpentine was not considered an inactive ingredient. A final decision on oil of turpentine depends on its status in the final monograph or on any position on inactive ingredients that the agency may take in the future.

The agency points out that the combination of aromatics for antitussive use was not considered as a "single active ingredient." Data on the aromatic ingredients were reviewed and demonstrated the antitussive effectiveness of menthol and camphor individually (as well as in combination with other aromatic ingredients), and the supportive contribution of eucalyptus oil. Likewise, in order to achieve Category I status for the combination of aromatic ingredients as nasal decongestants, the individual ingredients must be tested to show that they do provide a significant nasal decongestant effect when compared to a control. Additionally, in accordance with the agency's "General Guidelines for OTC Drug Combination Products, September 1978" cited above, Category I ingredients from the same therapeutic category that have the same mechanism of action may be combined in selected circumstances to treat the same symptoms or conditions if the combination meets the OTC combination drug policy in all respects, the combination offers some advantage over the active ingredients used alone, and the combination is, on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose.

In conclusion, the agency agrees with the Panel that the data for the combination of menthol, camphor, eucalyptus oil, thymol, cedar leaf oil, and nutmeg oil as nasal decongestants for application as an ointment or for steam inhalation are inadequate and, therefore, the combination is classified as Category III.

The agency's detailed comments and evaluation on the data are on file in the Dockets Management Branch (Ref. 2).

References

(1) Comment No. LET083, Docket No. 76N-052G, Dockets Management Branch.
(2) Letter from W.E. Gilbertson, FDA to G.F. Hoffnagle, Richardson-Vicks, Inc., coded LET084, Docket No. 76N-052G, Dockets Management Branch.

I. Comments on Dosages for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Combination Drug Products

60. Two comments pointed out a number of problems in combining an oral nasal decongestant with an analgesic-antipyretic because of what they described as "irreconcilable"

dosage schedules recommended by the Cough-Cold and the Internal Analgesic Panels. The comments stated that this situation existed because the Cough-Cold Panel had recommended fixed single dosages for the nasal decongestants phenylephrine and phenylpropanolamine for children 2 to under 6 years and 6 to under 12 years of age, and the Internal Analgesic Panel (in the draft of its report available at the time the Cough-Cold Panel's report was published) was recommending dosages for children 2 to under 4 years, 4 to under 7 years, 7 to under 9 years, 9 to under 11 years, and 11 to under 12 years of age.

In order to combine an oral nasal decongestant with an analgesic-antipyretic for use in children 2 to under 12 years of age, the Cough-Cold Panel's two fixed single dosages for children 2 to under 6 and 6 to under 12 years of age would have to be expanded to include an intermediate dosage for children 4 to under 6 years of age, or a dosage range would have to be allowed. For this reason, one comment proposed increasing the 12.5 mg-every-4-hour dosage of phenylpropanolamine recommended by the Panel for children 6 to under 12 years of age to 12.5 to 25 mg every 4 hours (or 25 mg every 8 hours), and increasing the dosage of 6.25 mg every 4 hours recommended by the Panel for children 2 to under 6 years of age to 6.25 to 12.5 mg every 4 hours (or 12.5 mg every 8 hours). The second comment recommended a dosage for phenylephrine every 4 hours of 2.5 mg for children 2 to under 4 years of age; 3.75 mg for children 4 to under 7 years of age; and 5 mg for children 7 to 9 years of age. This proposal would increase the 2.5 mg dosage of phenylephrine recommended by the Panel for children 4 and 5 years of age to 3.75 mg, and decrease the 5 mg dosage of phenylephrine recommended by the Panel for children 6 years of age to 3.75 mg.

As for the first comment's suggested dosage for phenylpropanolamine of 25 mg every 8 hours for children 6 to 12 years of age, and 12.5 mg every 8 hours for children 2 to under 6 years of age, the agency published a notice concerning the Panel's recommendation on the dosages of phenylpropanolamine in the **Federal Register** on October 28, 1977 (42 FR 56756). The notice stated that the adult dosage of 50 mg every 8 hours and equivalent children's dosages were provided only for timed-release dosage forms which would not be included in the monograph. Therefore, the Panel's recommended monograph was corrected to include only the dosages for conventional, immediate-release formulations. The reference to a dosage of 50 mg every 8 hours and equivalent children's dosages was deleted from the Panel's recommendations by the October 28, 1977 notice.

Because of studies indicating that certain dosages of phenylpropanolamine can cause elevations in blood pressure, the agency has not categorized phenylpropanolamine as a nasal decongestant in the tentative final monograph for OTC nasal decongestant drug products (50 FR 2220), but will, instead, address the safety of phenylpropanolamine for weight control use and nasal decongestant use in a future **Federal Register** publication. Before there can be any resolution of the "irreconcilable" dosage issue concerning combinations containing phenylpropanolamine preparations, the safety and effectiveness issues that have been raised must be addressed.

The agency recognizes that a problem of irreconcilable dosages would also occur with combinations containing an analgesic-antipyretic with pseudoephedrine, a Category I oral nasal decongestant, if the dosages are not changed. In the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products (to be published in a future issue of the **Federal Register**), the agency will propose that the minimal effective dose of 325 mg of aspirin, acetaminophen, and sodium salicylate for children 6 to 9 years of age can also be used as the minimal effective dose for children over 9 years of age (i.e., 9 to under 12). Because of the extension of the 325-mg minimal effective dose of aspirin, acetaminophen, and sodium salicylate to children over 9 years of age, combinations of an analgesic-antipyretic with pseudoephedrine are possible for children 6 to under 12 years of age with no changes in the Cough-Cold Panel's recommended dosages. Combinations are also possible for children 2 to under 4 years of age based on the Cough-Cold Panel's recommended dosages. However, no dosage formulation of the combination product could be used for children 4 to under 6 years of age because, in one case, if the analgesic is given at the recommended dosage, then the pseudoephedrine dosage would be too high for this age group, and in the other case, if pseudoephedrine is given at the recommended dosage, then the analgesic dosage would be too low. A similar situation exists for combination products containing phenylephrine hydrochloride and an analgesic-antipyretic, i.e., the recommended dosages could be used for children 2 to under 4 and 6 to under 12 years of age, but there would be a problem of irreconcilable dosages for children 4 to under 6 years of age.

The agency is not modifying the dosages for oral nasal decongestants at this time, but is inviting comments from interested persons on the problem of currently irreconcilable dosages for these combination products. The agency invites comments and the submission of data on dosage ranges for children for products containing oral phenylephrine, or pseudoephedrine for use in combination with analgesics, or for any other cough-cold ingredients for which there might be a problem concerning irreconcilable dosages when combined with analgesics. Other comments have been received in response to the tentative final monograph for OTC antihistamine (50 FR 2200), antitussive (48 FR 48576), and nasal decongestant (50 FR 2220) drug products, requesting that the agency revise pediatric dosages for combination drug products containing ingredients in these pharmacologic classes including when these ingredients are combined with internal analgesic-antipyretic ingredients. Because several rulemakings are affected by this issue, the agency has published a separate document discussing pediatric dosages for OTC cough-cold drug products and deferred all issues regarding pediatric dosages to that document. (See the **Federal Register** of June 20, 1988; 53 FR 23180.) Any amendments to currently proposed tentative final monographs will be addressed at that time.

J. Comments on Labeling for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Combination Drug Products

61. One comment objected to the Panel's recommendation "that combination products must be labeled to reflect all of the proven pharmacologic activities of each active ingredient in the combination" (41 FR 38325). The comment pointed out that such labeling would conflict with the Panel's recommendation that labeling include only those indications that are for concurrent symptoms. The comment stated that labeling that includes use of the product for a nonconcurrent symptom would confuse consumers and possibly encourage them to use a combination drug product when a single-ingredient product would suffice. The comment also objected to the Internal Analgesic Panel's recommendation that the labeling of

such combination products emphasize use of the product only when all such symptoms are present (42 FR 35370). The comment maintained that such labeling would be confusing and that a product containing an analgesic-antipyretic ingredient should not be avoided because a single symptom of only pain or fever is present rather than both symptoms. To clarify the apparent inconsistency in both the Panels' recommendations, the comment requested that the phrase "consistent with the recommended use of the product" be added to the Cough-Cold Panel's statement concerning the inclusion of all proven pharmacologic activities in the labeling of a drug product and that the phrase in § 343.20(d) (1), (2), (3), and (4) of the advance notice of proposed rulemaking for OTC internal analgesic drug products that states "* * * the product is labeled for the concurrent symptoms involved * * *" be replaced by the following statement: "The product must be labeled to reflect all of the proven pharmacological activities of the active ingredient(s) consistent with the recommended use of the product."

A second comment contended that drug products should be labeled with all the pharmacologic activities of a drug. The comment maintained that knowing all the activities of a drug causes consumers less confusion and is less expensive because there are times when a single drug can be used to relieve several symptoms. Thus, the consumer can avoid spending twice the money for two products when one product would suffice.

The agency notes there is no legal restriction that prevents "multi-use" labeling, i.e., labeling a drug product with some or all of the proven pharmacologic activities of the drug whether or not the conditions to be treated are related. For products that contain an ingredient with multi-use labeling, the labeling for each "different" use of the ingredient would have to be distinct and not confusing and would have to meet the requirements of the applicable OTC drug monographs in Part 330 in addition to the labeling requirements for OTC drugs in Subpart C of 21 CFR Part 201. Because of the labeling requirements and the need to provide information that is not confusing to consumers, the agency invites manufacturers to consult with FDA before labeling their products with multi-use labeling.

In the case of an OTC drug product that contains an ingredient with different pharmacologic actions that can treat related symptoms, those pharmacologic actions that are consistent with the intended use of the product appropriately may appear in the labeling but are not required to appear. Diphenhydramine hydrochloride is an example of such a drug. If diphenhydramine hydrochloride were reclassified as a Category I antitussive in the final monograph, a drug product containing diphenhydramine hydrochloride for the treatment of symptoms associated with the common cold could be labeled both as an antihistamine and an antitussive because these actions are consistent with the intended use of the product. However, if a manufacturer chose to promote only one of the pharmacologic actions of diphenhydramine (e.g., its antitussive action), the product would not be required to be labeled as both an antihistamine and an antitussive. In such a case, because the product is intended only for use as an antitussive, only information on the use of the drug as an antitussive need be included in the labeling.

Diphenhydramine hydrochloride also has another pharmacologic action (i.e., causes drowsiness) that allows it to be marketed OTC as a nighttime sleep-aid. For cough-cold combination drug products, the use of multi-use labeling is limited because it is unlikely that a specific combination of ingredients, e.g., an antihistamine-antitussive-internal analgesic combination (which relieves cold symptoms such as runny nose, sneezing, cough, and fever) could also be used to relieve other symptoms not related to the common cold, e.g., nighttime sleep-aid. Further, if combinations are labeled with multi-use labeling, all of the labeled uses must be indications that are consistent with Category I combinations. There are currently no Category I combinations involving cough-cold ingredients and nighttime sleep-aid ingredients.

The agency believes that the labeling for OTC analgesic-antipyretic and cough-cold ingredient combination drug products should reflect the principal intended use(s) of the product (e.g., pain reliever-fever reducer and nasal decongestant.) Such labeling must be consistent with the approved indications for all of the ingredients but should not necessarily contain all of the indications, particularly those indications that are not consistent with the concurrent use of the ingredients in the combination product.

In adopting an indications statement for an analgesic-antipyretic active ingredient with the indications statement(s) for the possible cough-cold active ingredients it could be combined with (e.g., an antihistamine, an antitussive), the agency has determined that an appropriate indications statement for the analgesic-antipyretic ingredient of a cough-cold product would be "For the temporary relief of minor aches, pains, headache, muscular aches, and fever associated with" (select one of the following: "the common cold" or "a cold") which would then be followed by the appropriate indication(s) for the cough-cold ingredient(s).

The agency recognizes that products containing an analgesic-antipyretic combined with an antihistamine, or a nasal decongestant, or both, may also be marketed for use in a target population that has hay fever/allergic rhinitis or sinusitis symptoms, but not cold symptoms. The agency has determined that an appropriate indications statement for the analgesic-antipyretic ingredient for such products would be "For the temporary relief of minor aches, pains, and headache" (followed by the labeling for antihistamines in § 341.72(b)(1) and/or the labeling for nasal decongestants in § 341.80(b)(1) (ii) or (iii), as appropriate).

Therefore, in § 341.85(b)(1) of this tentative final monograph, the agency is proposing that all permitted combinations of analgesic-antipyretic and cough-cold active ingredients, identified in § 341.40 that are marketed and labeled for relief of cough-cold symptoms must bear the following indications statement: "For the temporary relief of minor aches, pains, headache, muscular aches, and fever associated with the common cold" (followed by the appropriate indication(s) for the cough-cold active ingredient(s)). In addition, permitted combinations containing an analgesic-antipyretic and an antihistamine identified in § 341.40(a); an analgesic-antipyretic, an antihistamine, and an oral nasal decongestant identified in § 341.40(c); and an analgesic-antipyretic and an oral nasal decongestant identified in § 341.40(n) may also bear this indication. However, for products which are promoted for use in individuals with hay fever/allergic rhinitis or sinusitis symptoms, the following indications statement in § 341.85(b)(2) should be used: "For the temporary relief of minor aches, pains, and headache," (followed by the labeling for antihistamines in § 341.72(b)(1) and/or the labeling for nasal decongestants in § 341.80(b)(1) (ii) or (iii), as appropriate). Products which are promoted for relief of cough-cold symptoms in addition to hay fever/allergic rhinitis and/or sinusitis

symptoms must include both labeling statements in § 341.85(b) (1) and (2).

In conclusion, the agency believes that combination drug products may contain only those active ingredients that treat concurrent symptoms consistent with the intended use of the product. The agency finds it unnecessary to adopt the comment's suggestion that product labeling should be "consistent with the recommended use of the product," because the proposed labeling for combination products ensures that each component of the combination product conforms to the intended use of the product. The agency does not agree with the comment that the product must be labeled to reflect *all* of the proven pharmacological activities of the active ingredient(s) consistent with the recommended use of the product. There is no agency requirement that an OTC drug product be labeled with all of the proven pharmacological activities of its active ingredients. On the other hand, there is no regulation that prohibits multi-use labeling, i.e., the labeling of products to reflect all of the proven pharmacologic activities of its active ingredients. However, for combination drug products to be labeled with multi-use labeling, all of the labeled uses must be for Category I combinations. The OTC drug monographs provide the acceptable labeling of the product for OTC use, and the agency believes that the labeling proposed for combination products in this tentative final monograph adequately describes for consumers the appropriate concurrent symptoms for which the product is to be used.

62. One comment stated that warnings for combination products containing ingredients from several different pharmacologic groups should be consolidated in order to decrease the number of different statements that would be required for such products. Another comment requested that provision be made for combining indications for combination products containing ingredients from several different pharmacologic groups so that the resulting statement of indications is clear and understandable.

The agency agrees with the comments. For combination products that contain ingredients from several different pharmacologic groups, manufacturers may combine warnings, indications, and directions, respectively, to eliminate duplicative words or phrases so that the resulting information is clear and understandable. To clarify how this can be done, the agency is proposing a paragraph in the labeling section (§ 341.85) for permitted combinations in this tentative final monograph which states that indications, warnings, and directions, respectively, applicable to each active ingredient in the combination drug product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable. For example, the warning for an antihistamine in proposed § 341.72(c)(2) (50 FR 2216) "Do not take this product if you have asthma, glaucoma, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor," and the warning for an oral nasal decongestant in proposed § 341.80(c)(1)(i)(*c*) (50 FR 2239) "Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor" may be combined for an antihistamine-nasal decongestant combination product as follows: "Do not take this product if you have asthma, glaucoma, heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

In reviewing the warnings for different ingredients that could be present in possible combination products, the agency has determined that a conflict exists between the warning proposed for oral nasal decongestants (labeled for adult use) in § 341.80(c)(1)(b) that states: "Do not take this product for more than 7 days. If symptoms do not improve or are accompanied by fever, consult a doctor," and the warning to be proposed in a future issue of the **Federal Register** for internal analgesic ingredients (adult dosages) in § 343.50(c) that will state not to take this product for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor; and if pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition. A similar conflict exists between the warning proposed for oral nasal decongestants (labeled for children under 12 years of age) in § 341.80(d)(ii)(b) and the warning to be proposed for internal analgesic ingredients (children's dosages) in § 343.50(c)(2), which will limit the use of an internal analgesic for pain in children to 5 days. Because of the conflict between the respective warnings, the agency is proposing that the following specific warning be used for combinations containing an analgesic-antipyretic ingredient(s) and an oral nasal decongestant ingredient identified in § 341.40 (c), (f), (k), and (n) when labeled for adult use: "Do not take this product for more than 10 days. If symptoms do not improve or are accompanied by fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

The agency is also proposing the following warning for this combination when labeled for children 2 years to under 12 years of age, "Do not give this product to children for more than 5 days. If symptoms do not improve or are accompanied by fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor." The agency is further proposing a warning for this combination product when labeled for both adults and children 2 years of age to under 12 years of age: "Do not take this product for more than 10 days (for adults) or 5 days (for children). If symptoms do not improve or are accompanied by fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

An incompatibility also exists between the analgesic-antipyretic warnings discussed above and the warning for antitussives in § 341.74(c)(1) "A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor" (52 FR 30056). The agency is proposing that the following warning be used for combination drug products containing an antitussive and an analgesic-antipyretic ingredient(s) identified in § 341.40 (f) and (k) when labeled for adult use: "Do not take this product for more than 10 days. A persistent cough may be a sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by rash, persistent headache, fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor." The combined warning for children reads as follows: "Do not give this product to children for more than 5 days. A persistent cough may be sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by rash, persistent headache, fever that last for more than 3 days, or if new symptoms occur, consult a doctor." For products labeled for both adults and children, the proposed combined warning reads as follows: "Do not take this product for more than 10 days (for adults) or 5 days (for children). A persistent cough may be sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by rash, persistent

headache, fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

The warning proposed for expectorants in § 341.78(c)(3) in the tentative final monograph for OTC expectorant drug products "A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor," also conflicts with the warning for analgesic-antipyretics discussed above. The combined warnings to be used for combinations containing an expectorant and an analgesic-antipyretic ingredient(s) identified in § 341.40(m) when labeled for adults and/or children are the same warnings proposed above for combinations of an antitussive and an analgesic-antipyretic ingredient(s). The warnings for specific cough-cold combination drug products which differ from the warnings required for the individual ingredients are included in § 341.85(d) in this tentative final monograph.

The agency has also identified conflicts in that portion of the directions that deal with the lower age limits of use for children's dosages for some of the combinations identified in § 341.40. For example, the directions for an OTC antihistamine advises that a doctor be consulted for use in children under 6 years of age, while OTC analgesic-antipyretic ingredients may be given to a child as young as 2 years of age without consulting a doctor. The agency is concerned that when a combination product containing analgesic-antipyretic and cough-cold ingredients is labeled for use in children of a particular age group that each individual ingredient be generally recognized as safe for use in that particular age group. Therefore, the agency is proposing that when there is a difference in the directions established for the individual ingredients in a combination drug product, e.g., when the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph. Thus, in the above example, the product can be labeled only for use in children 6 years of age and over.

63. One comment disagreed with the Panel's classification of the word "multiaction" as a claim having no scientific foundation or meaning, or as being meaningless to the consumer as a labeling claim for cough-cold products (41 FR 38337). In the comment's opinion, this term is meaningful in a labeling claim for a combination product recommended for the relief of more than one symptom because such a product would have multiple actions and the term "multiaction" would indicate to the consumer a need to consider these actions. Therefore, the comment contended that it is inconsistent "to prohibit the use of one of the clearest, most direct words available to describe the product's potential" to the consumer. In view of this, the comment recommended that the word "multiaction" not be rejected as a term to be used in labeling claims for combination cough-cold products.

The word "multiaction" is not sufficiently specific to be included in the "statement of identity" or "indications" portions of the labeling required for OTC drug products. However, the agency has no objection to use of this word as a general, descriptive term in the labeling of drug products that combine ingredients from different therapeutic categories. Considering that the specific identity and use(s) of the drug product are spelled out in the statement of identity and indications, the word "multiaction" used elsewhere in the labeling would not be misleading and should be available to manufacturers as a matter of choice. Although this term does not appear in this tentative final monograph, the agency has no objection to its use in other portions of the labeling that are not regulated by the monograph.

64. A number of comments objected to the warning recommended by the Panel in § 341.85(d) for combination products containing aspirin: "This product contains aspirin and should not be taken by individuals who are sensitive to aspirin." Several of the comments stated that the warning was redundant and unnecessary because the listing of the active ingredients on the label suffices to disclose the presence of aspirin. Another comment stated that the labeling for aspirin should be addressed as part of the internal analgesic monograph and not in the cough-cold monograph. Two of the comments suggested that the word "allergic" be used instead of "sensitive" because the latter is misleading and the Panel intended to use the term "allergic."

The agency agrees that the labeling for aspirin should be addressed in the internal analgesic monograph and, therefore, is not addressing the specific requests stated by the comments in this document. The agency's conclusions on aspirin labeling will be stated as part of the rulemaking for OTC internal analgesic drug products. For these reasons, the Panel's recommendation in § 341.85(d) is not being included in this tentative final monograph.

The agency points out, however, that combination products containing cough-cold ingredients plus internal analgesic ingredients would need to conform to both monographs.

In addition, combination products that have aspirin or aspirin-containing drugs as the internal analgesic ingredient must bear the Reye syndrome warning in accord with 21 CFR 201.314(h) (1) through (4). The regulation also states that OTC drug products covered by the regulation and labeled solely for use by children (pediatric products) shall not recommend the product for use in treating flu or chicken pox. In the **Federal Register** of June 9, 1988 (53 FR 21633), the agency published a final rule making this Reye syndrome labeling provision permanent. Therefore, even though this tentative final monograph is only a proposed rule, any currently marketed cough-cold combination product that contains aspirin or an aspirin-containing ingredient must bear the appropriate Reye's syndrome labeling in accord with 21 CFR 201.314(h).

65. One comment expressed concern that products recommended by the Panel in § 341.40 (a), (c), (j), (m), and (o) containing cough-cold ingredients in combination with analgesic-antipyretic ingredients or local anesthetic ingredients might require reformulation and relabeling more than once. The comment explained that this could happen if the a cough-cold monograph became final before the other applicable monograph(s). Thus, cough-cold combinations containing internal analgesic ingredients such as aspirin might have to be reformulated and relabeled to comply with the subsequent internal analgesic final monograph. To avoid this, the comment proposed that the effective date for reformulation and relabeling of combination products containing ingredients from more than one monograph should be the effective date of the last applicable final monograph.

The agency's policy is that an OTC drug product, whether single ingredient or combination, must conform to an applicable monograph on the effective date of the final monograph. Thus, the cough-cold component of a combination product described above would have to meet all of the requirements of the cough-cold monograph upon its effective date. The agency acknowledges that a combination product containing ingredients covered by different monographs might require reformulation

and relabeling more than once. However, the comment's suggested approach could result in the continued marketing of an ingredient of questionable safety or an ingredient not proven effective (nonmonograph condition) past the effective date of an applicable final monograph, or the failure to include required labeling on the product, only because the ingredient was included in a combination product with another ingredient covered by a monograph that had yet to take effect. Therefore, the comment's proposal is not accepted.

66. One comment pointed out "an apparent contradiction in the labeling requirements for a bronchodilator combined with an expectorant." The Panel's recommended warning for bronchodilator-expectorant combinations in § 341.85(c) states "This product should be used only for cough associated with asthma" (41 FR 38423). The comment noted, however, that the following warning is included in the labeling requirements for expectorant drug products in § 341.78(b)(2): "Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema or where cough is accompanied by excessive secretions except under the advice and supervision of a physician" (41 FR 38422). The comment requested that the word "asthma" be deleted from the Panel's recommended warning in § 341.78(b)(2) to resolve an apparent inconsistency concerning the use of the combination by asthmatics that would result from placing both label warnings (§§ 341.85(c) and 341.78(b)(2)) on the combination product.

The inclusion of the word "asthma" in the warning in § 341.78(b)(2) does not conflict with the warning for bronchodilator-expectorant combinations in § 341.85(c). The Panel's inclusion of the word "asthma" in its warning in § 341.78(b)(2) only emphasizes that products containing expectorants, even in combination with a bronchodilator, should not be used in patients with asthma "unless directed by a doctor." This is consistent with the Panel's recommended warning for bronchodilators in § 341.76(b)(1) that states "Do not take this product unless a diagnosis of asthma has been made by a physician." In addition, the agency agrees with the Panel that cough-cold drug products which contain an expectorant but do not contain a bronchodilator should not be available OTC for use by consumers with asthma except as directed by a doctor. Therefore, the agency does not agree that the word "asthma" should be deleted from the warning recommended by the Panel in § 341.78(b)(2).

However, after reviewing all of the warnings proposed for bronchodilator drug products (47 FR 47527), the agency concludes that the Panel's recommended warning in § 341.85(c) "This product should be used only for cough associated with asthma," in addition to the agency's proposed warning in § 341.76(b)(1) "Do not take this product unless a diagnosis of asthma has been made by a physician," is unnecessarily repetitious. Therefore, the warning recommended by the Panel in § 341.85(c) is not being proposed in this tentative final monograph.

K. Comments on Testing Guidelines for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Combination Drug Products

67. Several comments disagreed with the Panel's testing procedures for Category III combination products. One comment stated that the Panel had omitted a criterion for the testing of some combinations containing ingredients with overlapping pharmacologic activities, e.g., an antihistamine and an anticholinergic. The comment submitted a proposed criterion and testing procedure for such combinations.

As noted in comment 29 above, tentative final and final monographs will no longer contain recommended testing guidelines. Therefore, comments regarding Category III testing guidelines will not be addressed in this document. However, the agency will meet with industry representatives at their request to develop testing guidelines for those conditions which industry is interested in upgrading, and to advise industry on the adequacy of proposed protocols. (See also part II. paragraph A.2. below—*Testing of Category II and Category III conditions.*)

II. The Agency's Tentative Adoption of the Panel's Report

A. Summary of Combinations Categorizations and Testing of Category II and Category III Conditions

1. *Summary of combinations categorizations.* The agency has reviewed all claimed active ingredients and combinations submitted to the Panel, as well as other data and information available at this time, and is proposing the recategorization of eight combinations, i.e., the combination of an analgesic-antipyretic(s), an oral antitussive, an oral nasal decongestant, and an antihistamine; the combination of an antihistamine (if the antihistamine is also a Category I antitussive) and an oral antitussive; the combination of an oral antitussive (if the antitussive is also a Category I antihistamine) and an antihistamine; the combination of theophylline and a sympathomimetic bronchodilator; combinations containing more than two active ingredients from the same pharmacologic group; combinations containing phenobarbital and any central nervous system stimulant cold, cough, allergy, bronchodilator, or antiasthmatic ingredient(s); the combination of 1-desoxyephedrine and aromatics in a inhaler as a topical nasal decongestant; and the combination of menthol, camphor, and eucalyptus oil in an ointment as a topical antitussive. The agency is proposing the classification of seven combinations that were not classified by the Panel, i.e., the combination of an analgesic-antipyretic(s), an oral antitussive, and an oral nasal decongestant; the combination of an oral antitussive and an analgesic-antipyretic(s); the combination of an analgesic-antipyretic(s) and an expectorant; the combination of an oral nasal decongestant, an oral antitussive, and an anesthetic/analgesic in a solid dosage form; the combination of an anticholinergic, an antihistamine, and an oral nasal decongestant; combinations containing caffeine (to combat lethargy) and cough-cold preparations not containing antihistamines; and the combination of phenylpropanolamine, ephedrine, and caffeine. In addition, the agency is proposing the classification of the following fourteen combinations containing cough-cold and oral health care active ingredients that were not classified by either the Cough-Cold or Oral Cavity Panels: a debriding agent/oral wound cleanser and an oral antitussive; a debriding agent/oral wound cleanser and an antihistamine; an astringent and an oral antitussive; an astringent and an antihistamine; an oral antitussive and an oral demulcent; an oral nasal decongestant and an oral demulcent; an oral nasal decongestant, an oral antitussive, and an oral demulcent; an expectorant and an oral anesthetic/analgesic; an expectorant and an oral demulcent; an antihistamine and an oral anesthetic/analgesic; an antihistamine and an oral demulcent; an oral antitussive or an oral nasal decongestant, an oral anesthetic/analgesic, and an oral demulcent; and an oral nasal decongestant, an oral antitussive, an oral anesthetic/analgesic, and an oral demulcent. The last ten of these combinations are for products in a solid dosage form to be dissolved in the mouth and swallowed.

For the convenience of the reader, the following table is included as a summary of the categorizations by the Panel and the proposed classification by the agency.

The combination drug products that are listed below are intended for oral use unless otherwise stated. Because antitussives, bronchodilators, and nasal decongestants may be administered orally or topically, the agency is identifying these drugs as oral or topical for clarity.

Cough-cold combinations	Panel	Agency
Analgesic-antipyretic(s) and antihistamine	I	I
Analgesic-antipyretic(s) and oral antitussive	[1] N.C.	I
Analgesic-antipyretic(s) and expectorant	N.C.	I
Analgesic-antipyretic(s) and oral nasal decongestant	I	I
Analgesic-antipyretic(s) and oral nasal decongestant and antihistamine	I	I
Analgesic-antipyretic(s) and oral antitussive and oral nasal decongestant	N.C.	I
Analgesic-antipyretic(s) and oral antitussive and oral nasal decongestant and antihistamine	III	I
Antihistamine and oral antitussive (if labeled "May cause market drowsiness")	I	I
Antihistamine and oral nasal decongestant	I	I
Antihistamine and oral antitussive and oral nasal decongestant	I	I
Oral antitussive and expectorant (if labeled for nonproductive cough)	I	I
Oral antitussive and oral nasal decongestant	I	I
Oral antitussive and expectorant and oral nasal decongestant (if labeled for nonproductive cough)	I	I
Oral antitussive and anesthetic/analgesic (if available only in a solid dosage form)	I	I
Oral bronchodilator and expectorant (if labeled for cough associated with asthma)	I	I
Expectorant and oral nasal decongestant	I	I
Oral nasal decongestant and oral anesthetic/analgesic (if available in a solid dosage form)	I	I
Oral nasal decongestant and oral antitussive and oral anesthetic/analgesic (if available in a solid dosage form)	N.C.	I
Oral antitussive and oral demulcent (if available in a solid dosage form)	N.C.	I
Oral nasal decongestant and oral demulcent (if available in a solid dosage form)	N.C.	I
Oral nasal decongestant and oral antitussive and oral demulcent (if available in a solid dosage form)	N.C.	I
Oral antitussive and oral anesthetic/analgesic and oral demulcent (if available in a solid dosage form)	N.C.	I
Oral nasal decongestant and oral anesthetic/analgesic and oral demulcent (if available in a solid dosage form)	N.C.	I
Oral nasal decongestant and oral antitussive and oral anesthetic/analgesic and oral demulcent (if available in a solid dosage form)	N.C.	I
Oral antitussive and debriding agent/oral wound cleanser	N.C.	II
Antihistamine and debriding agent/oral wound cleanser	N.C.	II
Oral antitussive and astringent	N.C.	II
Antihistamine and astringent	N.C.	II
Analgesic-antipyretic(s) and oral bronchodilator	II	II
Anticholinergic and expectorant	II	II
Antihistamine and expectorant	II	II
Antihistamine (if antihistamine is also a Category I antitussive) and oral antitussive	II	III
Oral antitussive (if antitussive is also a Category I antihistamine) and antihistamine	II	III
Oral bronchodilator and anticholinergic	II	II
Oral bronchodilator and antihistamine	II	II
Oral bronchodilator and oral antitussive (if labeled for cough associated with asthma)	II	II
Theophylline and sympathomimetic bronchodilator (e.g., ephedrine)	I	II
Antihistamine and anticholinergic	III	[2] II
Antihistamine and oral anesthetic/analgesic	N.C.	III
Antihistamine and oral demulcent	N.C.	III
Expectorant and oral anesthetic/analgesic	N.C.	III
Expectorant and oral demulcent	N.C.	III
Antihistamine and nasal decongestant (administered topically as spray or drops)	III	III
Oral antitussive and bronchodilator used as an antitussive (if labeled for cough not associated with asthma)	III	III
Oral antitussive and expectorant (if labeled for productive cough)	III	III
Oral antitussive and expectorant and oral nasal decongestant (if labeled for productive cough)	III	III
Analgesic-antipyretic(s) and oral antitussive and expectorant and oral nasal decongestant	III	III
Anticholinergic and antihistamine and oral nasal decongestant	N.C.	[2] II
Atropine and oral nasal decongestant	III	[2] II
Expectorant and oral bronchodilator used as an antitussive (if labeled for cough not associated with asthma)	III	III
Combinations containing Category I ingredients from different pharmacologic groups if any ingredient is at less than the minimum effective dosage (unless the ingredient(s) are being used to treat the same symptom).	II	II
Combinations containing 2 or more ingredients at less than the minimum effective dosage and used to treat the same symptom (labeling claim) (even if it contains Category I ingredients from different pharmacologic groups).	III	III
Combinations containing more than 2 active ingredients from the same pharmacologic group	II	III
Combinations containing an antihistamine for the relief of symptoms of allergic rhinitis and an additional antihistamine which is added exclusively for sedation, and the product contains labeling which represents the additional antihistamine as a sleep-aid..	II	II
Combinations containing an antihistamine with a sleep-aid claim	III	III
Combinations containing a Category III ingredient or labeling and no Category II ingredient or labeling	III	III
Combinations containing 2 Category I ingredients from the same pharmacologic group	III	III
Combinations containing 2 Category I ingredients from the same pharmacologic group if either or both ingredients are at less than the minimum effective dosage.	III	III
Combinations containing a corrective (an active ingredient specifically intended to counteract a side effect of other ingredients in the product), e.g., caffeine, and any cold, cough, allergy, bronchodilator, or antiasthmatic ingredient(s) (except for the combination immediately below).	III	III
Combinations containing phenobarbital (8 mg) (as a stimulant corrective) and any central nervous system stimulant cold, cough, allergy, bronchodilator, or antiasthmatic ingredient(s) such as theophylline and ephedrine.	III	II
Combinations containing several claimed active ingredients which are mixtures of volatile substances with overlapping pharmacologic activities for which a minimum effective dosage cannot be established for one or more of the ingredients when tested alone (except for the combination immediately below).	III	III
1-Desoxyephedrine and aromatics (camphor, menthol, methyl salicylate, bornyl acetate, and lavender oil) in an inhaler as a topical nasal decongestant.	III	I
Combinations containing 4 or more ingredients from different pharmacologic groups (except for the combination of an analgesic-antipyretic and oral antitussive and oral nasal decongestant and antihistamine described above).	III	III

Cough-cold combinations	Panel	Agency
Combinations containing a stimulant, e.g., caffeine (at a fully effective level), and any cold, cough, allergy, bronchodilator, or antiasthmatic ingredient(s).	II	II
Combinations containing caffeine (15-30 mg) to combat lethargy (not as a sedative corrective) and cold preparations not containing antihistamines.	N.C.	II
Combinations containing vitamin C and cold, cough, allergy, bronchodilator, or antiasthmatic ingredient(s) for prevention or treatment of the common cold.	III	III
Combinations containing any vitamins with labeling claims for prevention or treatment of the common cold	II	II
Phenylpropanolamine and ephedrine and caffeine	N.C.	II
Caffeine and ephedrine or pseudoephedrine	N.C.	II
Caffeine and phenylpropanolamine	N.C.	II
Menthol and camphor and eucalyptus oil and thymol and cedar leaf oil and nutmeg oil (myristica oil) in a suitable vehicle for steam inhalation or topical use as a nasal decongestant.	III	III
Menthol and camphor and eucalyptus oil in a suitable ointment vehicle as a topical antitussive	III	I
Menthol and eucalyptus oil in a lozenge as a topical antitussive	III	III
Methol and camphor and eucalyptus oil and tincture of benzoin and polyoxyethylene dodecanol for use in a steam vaporizer as an antitussive.	III	III
Promethazine hydrochloride (if labeled for relief of symptoms of the common cold) may be used as the antihistamine in the above Category I combinations that contain cough-cold and/or analgesic-antipyretic ingredients.	I	I

[1] N.C.—Not classified by Panel.
[2] Combination is classified as Category II because of nonmonograph status of anticholinergics (50 FR 46587).

2. *Testing of Category II and Category III conditions.* The Panel recommended testing guidelines for cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products (41 FR 38327 and 38418). The agency is offering these guidelines as the Panel's recommendations without adopting them or making any formal comment on them. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any active ingredient or combination included in the review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). This policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the combinations section of the Panel's report and recommended monograph with the changes described in the summary below. A summary of the changes made by the agency follows.

1. For clarity, the agency is specifying in the tentative final monograph in § 341.40 and § 341.85 whether antitussives, bronchodilators, and nasal decongestants are for oral or topical use. (See comment 39 above.)

2. The agency is amending § 341.40 (j) and (o) to state that any single ingredient in § 356.10 (Category I anesthetic/analgesic active ingredients identified in the monograph for oral health care drug products) may be combined with an oral antitussive or an oral nasal decongestant in a solid dosage form to be dissolved in the mouth and swallowed. Additionally, to be consistent with the language used in the oral health care drug products report, the term "oral anesthetic/analgesic" is used in this document rather than the term "local anesthetic or local analgesic."

Additionally, the agency has examined other combination drug products containing cough-cold and oral health care active ingredients which were not reviewed by the Panel and is proposing to include the following as Category I combinations in new paragraphs u through z in § 341.40: an oral antitussive and an oral demulcent in a solid dosage form; an oral nasal decongestant and an oral demulcent in a solid dosage form; an oral antitussive, an oral nasal decongestant, and an oral demulcent in a solid dosage form; an oral antitussive, an oral anesthetic/analgesic, and an oral demulcent in a solid dosage form; an oral nasal decongestant, an oral anesthetic/analgesic, and an oral demulcent in a solid dosage form; and an oral nasal decongestant, an oral antitussive, an oral anesthetic/analgesic, and an oral demulcent in a solid dosage form. The following combinations are proposed as Category II: an antihistamine and an astringent; an oral antitussive and an astringent; an antihistamine and a debriding agent/oral wound cleanser; and an oral antitussive and a debriding agent/oral wound cleanser. The following combinations in a solid dosage form are proposed as Category III: an antihistamine and an oral anesthetic/analgesic; an antihistamine and an oral demulcent; an expectorant and an oral anesthetic/analgesic; and an expectorant and an oral demulcent. The agency will discuss combinations that include oral antimicrobials in the antimicrobial segment of the tentative final monograph for OTC oral health care drug products, to be published in a future issue of the **Federal Register**. (See comment 39 above.)

3. The agency is proposing a Category I classification of combination drug products containing an oral antitussive, an oral nasal decongestant, and an anesthetic/analgesic, provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed. (See comment 40 above.)

4. The agency is reclassifying from Category II to Category III combination drug products containing an oral antitussive (if the antitussive is also a Category I antihistamine) and an antihistamine and combination drug products containing an antihistamine (if the antihistamine is also a Category I antitussive) and an oral antitussive. (See comment 43 above.)

5. The agency is classifying in Category III combination drug products containing a nasal decongestant and an antihistamine administered topically in a nasal spray or drops. However, the specific combination product containing phenylephrine hydrochloride (a nasal decongestant) and methapyrilene hydrochloride (an antihistamine) in a nasal spray has been placed in Category II because methapyrilene-containing drug products are not generally recognized as safe. (See comment 51 above.)

6. The agency concludes that the combination of an anticholinergic, an oral nasal decongestant, and an antihistamine satisfies the criteria for a Category III combination. However, because at this time, there are no Category I (monograph) anticholinergics

in the final rule for OTC anticholinergic drug products (published in the **Federal Register** of November 8, 1985; 50 FR 46582), all OTC combination drug products containing anticholinergic ingredients (including the above mentioned combination) are classified as Category II (nonmonograph) conditions in this tentative final monograph. (See comment 53 above.)

7. Based on the Internal Analgesic Panel's Category I classification of a combination drug product containing an expectorant and an analgesic-antipyretic (42 FR 35493), the agency is proposing that the combination be classified in Category I in this tentative final monograph. [This combination was not classified by the Cough-Cold Panel.]

8. The Internal Analgesic Panel, stating that there is a small percentage of the population for whom buffered aspirin produces a lower incidence of gastric intolerance and who might therefore derive some benefit from buffered aspirin, classified in Category I buffered aspirin products, i.e., those containing aspirin combined with buffering ingredients (correctives) and those containing aspirin combined with antacids (42 FR 35469). In the tentative final monograph for OTC internal analgesic drug products, to be published in a future issue of the **Federal Register**, the agency will include buffered aspirin and aspirin and antacid combinations in the monograph. This tentative final monograph for cough-cold combination drug products proposes that buffered aspirin and aspirin and antacid combination drug products may be combined with cough-cold active ingredients as identified in § 341.40 "Permitted combinations of active ingredients" provided the product is labeled according to § 341.85.

Additionally, this document proposes that for combination drug products containing an analgesic-antipyretic ingredient(s) and a cough-cold active ingredient(s), that are marketed and labeled for relief of cough-cold symptoms, the indications statement for the analgesic-antipyretic portion of the product is as follows: "For the temporary relief of minor aches, pains, headaches, muscular aches, and fever associated with" (select one of the following: "the common cold" or "a cold") (followed by the appropriate indication(s) for the cough-cold ingredient(s).) However, for drug products containing an analgesic-antipyretic combined with an antihistamine and/or an oral nasal decongestant as identified in § 341.40 (a), (c), and (n) which are promoted for use in individuals with hay fever/allergic rhinitis or sinusitis symptoms, the following indication should be used: "For the temporary relief of minor aches, pains, and headaches" (followed by the labeling for antihistamines in § 341.72(b)(1) and/or the labeling for nasal decongestants in § 341.80(b)(1) (ii) or (iii), as appropriate). Products which are promoted for relief of cough-cold symptoms in addition to hay fever and/or sinusitis symptoms must include both labeling statements. (See comment 61 above.)

9. The agency is reclassifying from Category III to Category I combination drug products containing analgesic-antipyretic(s), an oral antitussive, an antihistamine, and an oral nasal decongestant. Additionally, based on the data on the above combination, the agency is also classifying in Category I combination drug products containing analgesic-antipyretic(s) (as identified above), an oral antitussive, and an oral nasal decongestant and combination drug products containing an oral antitussive and analgesic-antipyretic(s) (as identified above). (See comment 47 above.)

10. The agency is reclassifying from Category III to Category I combination drug products containing menthol (2.6 to 2.8 percent), camphor (4.7 to 5.3 percent), and eucalyptus oil (1.2 to 1.3 percent) in a suitable ointment vehicle as a topical antitussive combination drug product. (See comment 56 above.)

11. The agency is reclassifying from Category III to Category I combination drug products containing 1-desoxyephedrine and aromatics (camphor, menthol, methyl salicylate, bornyl acetate, and lavender oil) as a topical nasal decongestant (administered by a nasal inhaler). (See comment 55 above.)

12. The agency is reclassifying from Category I to Category II combination drug products containing theophylline and ephedrine. Therefore, the Panel's recommendation in § 341.40(k) is not being included in this tentative final monograph. Additionally, the agency is classifying in Category II any combination drug product that contains theophylline. This includes, but is not limited to, combinations of theophylline and ephedrine; combinations of theophylline, ephedrine, and phenobarbital; and combinations of theophylline, ephedrine, and an expectorant. (See comment 54 above.)

13. The agency is classifying the following combination drug products in Category II: phenylpropanolamine, ephedrine, and caffeine; caffeine in combination with ephedrine or pseudoephedrine; and phenylpropanolamine in combination with caffeine. FDA determined that such products are new drugs and are required to be the subject of an approved NDA. (See the **Federal Registers** of August 13, 1982 (47 FR 35344), November 18, 1983 (48 FR 52513), and June 29, 1984 (49 FR 26814).)

14. The agency is reclassifying phenobarbital 8 mg from Category III to Category II as a stimulant corrective. (See comment 49 above.)

15. The agency is classifying caffeine at a dosage of 15 to 30 mg in Category III when included in cough-cold drug preparations to combat lethargy. (See comment 50 above.)

16. The Panel recommended a Category I classification for the prescription drug promethazine hydrochloride as an antihistamine in its advance notice of proposed rulemaking (41 FR 38390). Because of concerns regarding adverse reactions on the central nervous system, the agency dissented from this recommendation in the preamble to the Panel's report (41 FR 38312). Subsequently, data were submitted to the agency to alleviate these concerns, but not sufficient to justify agreeing with the Panel's Category I classification of promethazine hydrochloride as a single ingredient (Ref. 1). Therefore, general recognition of the safety of promethazine hydrochloride as a single ingredient has not been adequately established.

Promethazine hydrochloride has not been used extensively on a long-term basis as a single ingredient for antihistamine/allergic rhinitis/anti-allergy use. The agency believes that consumers who use OTC antihistamines to treat the symptoms of allergic rhinitis use these products on a long-term basis because the symptoms of allergic rhinitis usually occur for extended periods of time. The major use of promethazine hydrochloride as a prescription drug is in combination drug products for relief of acute cough/cold symptoms on a short-term basis. The possibility that the rare, but serious adverse reaction of the central nervous system known as tardive dyskinesia will not occur if promethazine hydrochloride is used on a long-term basis in a single ingredient OTC antihistamine drug product has not been adequately demonstrated. Therefore, the agency proposed a Category III classification for promethazine hydrochloride in the tentative final monograph for OTC antihistamine drug products published in the **Federal Register** on January 15, 1985 (50 FR 2206). The agency will address the comments received in

response to that tentative final monograph on single ingredient use of promethazine in the final monograph for OTC antihistamine drug products in a future issue of the **Federal Register**.

The agency has also reviewed data and information on combination drug products containing promethazine hydrochloride that are used extensively on a prescription basis for treating symptoms of the common cold (Refs. 1 and 2). These data and information indicate that such short-term use of promethazine hydrochloride in these products is safe. Under conditions of short-term use for the relief of cold symptoms, the possibility that tardive dyskinesia might occur is no longer a concern. Therefore, the agency is proposing a Category I classification of promethazine hydrochloride in combination with other cough-cold and/or analgesic-antipyretic ingredients as provided for antihistamine active ingredients in § 341.40 (a) through (f) of this tentative final monograph. (See § 341.40(t) in this document.)

In accordance with the enforcement policy set out in 21 CFR 330.13, and with FDA's Compliance Policy Guide (Ref. 3), promethazine hydrochloride combinations may now be marketed OTC under the conditions set out in this tentative final monograph. Such marketing, pending issuance of the final monograph, is subject to the risk that the Commissioner may adopt a different position in the final monograph that could require relabeling, recall, or other regulatory action. Marketing of such a product with labeling not in accord with the tentative final monograph also may result in regulatory action against the product, the marketer, or both.

As with other combination drug products, the labeling of combination drug products containing promethazine hydrochloride must include those indications and pharmacologic actions that are consistent with the intended use of the product; however, labeling indications related to the antihistamine (promethazine hydrochloride) component of the combination product may indicate use only for the treatment of symptoms of the common cold. Such indications are specified in § 341.72(b)(2) of the tentative final monograph for OTC antihistamine drug products. The agency recognizes that combinations of an antihistamine and a nasal decongestant are often used on a long-term basis to treat symptoms of allergic rhinitis. In the case of a combination drug product containing promethazine hydrochloride and a nasal decongestant, the labeling cannot contain indications for allergic rhinitis specified in § 341.72(b)(1) nor any other labeling in any area of the label or packaging that might imply use in treating symptoms of allergic rhinitis. Such labeling restriction will ensure short-term rather than long-term use on an OTC basis of products containing promethazine.

The Panel recommended the following oral dosage schedule for promethazine hydrochloride: For adults, the dosage is 6.25 to 12.5 mg every 8 to 12 hours, not to exceed 37.5 mg in 24 hours. For children 6 to under 12 years, the dosage is 3.125 to 6.25 mg every 8 to 12 hours, not to exceed 18.75 mg in 24 hours. The Panel recommended that a dosage of 1.56 to 3.125 mg every 8 to 12 hours, not to exceed 9.375 mg in 24 hours be included under professional labeling for children 2 to under 6 years of age. For children under 2 there is no recommended dosage except under the advice and supervision of a physician (41 FR 38390).

The Panel's recommended dosage interval (i.e., 8 to 12 hours) does not allow promethazine hydrochloride in an immediate release dosage form to be combined with other cough-cold active ingredients. However, based on the Panel's conclusion that 6.25 mg is the minimum effective OTC dose for promethazine (41 FR 38390), and past FDA approved labeling for promethazine-containing drug products that recommend a dosage of up to 4 times daily (Ref. 4), and the current approved NDA labeling for the innovator promethazine-containing combination drug product that provides for a dosage of 6.25 mg every 4 to 6 hours (Ref. 4), the agency is proposing an adult dosage for promethazine hydrochloride of 6.25 mg every 4 to 6 hours, not to exceed 37.5 mg in 24 hours (and corresponding children's dosages). This revised dosage schedule will allow promethazine hydrochloride to be combined with other cough-cold active ingredients, as proposed in this tentative final monograph.

In addition to the general labeling required for antihistamine drug products in § 341.72 (a) and (c)(1) (see 50 FR 2216 and 52 FR 31913), the following labeling statements and revisions are required for combination drug products containing promethazine hydrochloride:

(1) Based on approved labeling for prescription drug products containing promethazine hydrochloride, the warning in § 341.72(c)(2) is modified to read "Do not take this product if you have asthma, glaucoma, emphysema, liver disease, seizures, chronic pulmonary disease, shortness of breath, difficulty in breathing, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor," and the warning in § 341.72(c)(6)(i) is modified to read "Do not give this product to children who have asthma, liver disease, seizures, or glaucoma unless directed by a doctor" (Ref. 4).

(2) The warning concerning drowsiness in § 341.72(c)(4) or (6)(iii) is required (see 52 FR 31913).

(3) The directions for use are "Adults: Oral dosage is 6.25 milligrams every 4 to 6 hours, not to exceed 37.5 milligrams in 24 hours. Children 6 to under 12 years of age: oral dosage is 3.125 milligrams every 4 to 6 hours, not to exceed 18.75 milligrams in 24 hours. Children under 6 years of age: Consult a doctor."

The modified warnings and directions for drug products containing promethazine hydrochloride appear in this document in § 341.85(d)(4) and § 341.85(e), respectively.

In addition, dosage information for the promethazine hydrochloride component of combination drug products containing promethazine hydrochloride for use in children 2 to under 6 years of age is included under professional labeling in § 341.90(r). Such dosage information is provided to health professionals but not to the general public as follows:

(r) *For combination drug products containing promethazine hydrochloride as identified in § 341.40(s).* Children 2 to under 6 years of age: oral dosage is 1.56 milligrams every 4 to 6 hours, not to exceed 9.36 milligrams in 24 hours.

References

(1) Comment Nos. C00188 and CP0002, Docket No. 76N-052H, Dockets Management Branch.

(2) Unpublished data obtained from the National Prescription Audit and the National Disease and Therapeutic Index data systems, OTC Volume 04HTFM, Docket No. 76N-052H, Dockets Management Branch.

(3) Food and Drug Administration Compliance Policy Guide 7132b.16, Docket No. 78D-0322, Dockets Management Branch.

(4) Copies of FDA-approved labeling from NDA 8-306, and 8-306/S-010 and S-011, OTC Volume 04GTFM, Docket No. 76N-052G, Dockets Management Branch.

17. The agency is adding to § 341.85 a "Statement of identity" paragraph (designated as § 341.85(b)), an "Indications" paragraph (designated as § 341.85(c)), a "Warnings" paragraph (designated as § 341.85(d)), and a "Directions" paragraph (designated as § 341.85(e)) to conform with the format of other recently published tentative final monographs. Inclusion of the new paragraphs has necessitated a redesignation of the Panel's warning in § 341.85(a) to 341.85(d)(5). The agency is also redesignating Subpart D as Subpart

C and placing the labeling sections of the monograph in Subpart C.

18. In § 341.85(a) the agency is proposing that indications, warnings, and directions, respectively, applicable to each active ingredient of the combination product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable. For combination products for which the labeling (i.e., statement of identity, indications, and warnings) in the individual applicable monographs conflicts or is inappropriate, the agency is proposing specific labeling for such combinations in § 341.85. Further, the agency is also proposing that when there is a difference in the directions established for the individual ingredients in the combination drug product, e.g., when the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph. (See comment 62 above.)

19. The agency is deleting the signal word "Caution" from the Panel's warning in § 341.85(a) (redesignated as § 341.85(d)(5)) for an antihistamine combined with an antitussive, i.e., "Caution: May cause marked drowsiness." In addition, upon petition, the agency will consider deletion of the word "marked" from this warning provided adequate data are submitted to demonstrate that the combination product does not cause a significant increase in drowsiness as compared with each active ingredient when tested alone. The petition and the data it contains will be maintained in a permanent file for public review in the Dockets Management Branch.

20. The agency is deleting the warning for bronchodilator-expectorant combination drug products recommended by the Panel in § 341.85(c), "This product should be used only for cough associated with asthma." (See comment 66 above.)

21. The agency is deleting the warning recommended by the Panel in § 341.85(d), "This product contains aspirin and should not be taken by individuals who are sensitive to aspirin." (See comment 64 above.)

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96–354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products, a period of 120 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has carefully considered the potential environmental effects of this action. FDA 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, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Interested persons may, on or before December 12, 1988, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before December 12, 1988. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before August 14, 1989, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written, comments on the new data may be submitted on or before October 12, 1989. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on October 14, 1989. Data submitted after the closing of

the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 341

Labeling; Over-the-counter drugs; Cold, cough, allergy, bronchodilator, and antiasthmatic combinations.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, and under 21 CFR 5.11, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 341 as follows:

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for Part 341 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

2. In Subpart B, new § 341.40 is added, to read as follows:

§ 341.40 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the established dosage limits and the product is labeled in accordance with § 341.85:

(a) Any single antihistamine active ingredient identified in § 341.12 may be combined with any single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or aspirin and antacid combinations.

(b) Any single antihistamine active ingredient identified in § 341.12 may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a).

(c) Any single antihistamine active ingredient identified in § 341.12 may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any single analgesic-antipyretic active ingredients, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or aspirin and antacid combinations.

(d) Any single antihistamine active ingredient identified in § 341.12 may be combined with any single oral antitussive active ingredient identified in § 341.14(a) provided that the product is labeled according to § 341.85(d)(5).

(e) Any single antihistamine active ingredient identified in § 341.12 may be combined with any single oral antitussive active ingredient identified in § 341.14(a) and any single oral nasal decongestant active ingredient identified in § 341.20(a).

(f) Any single antihistamine active ingredient identified in § 341.12 may be combined with any single oral antitussive active ingredient identified in § 341.14(a) and any single oral nasal decongestant active ingredient identified in § 341.20(a) and any single analgesic-antipyretic active ingredients or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or aspirin and antacid combinations.

(g) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single expectorant active ingredient identified in § 341.18.

(h) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a).

(i) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any single expectorant active ingredient identified in § 341.18.

(j) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.10 of this chapter provided that the product is available in a solid dosage form to be dissolved in the mouth and swallowed.

(k) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any single analgesic-antipyretic active ingredients or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or aspirin and antacid combinations.

(l) Any single oral bronchodilator active ingredient identified in § 341.16 (a), (b), (c), and (h) may be combined with any single expectorant active ingredient identified in § 341.18.

(m) Any single expectorant active ingredient identified in § 341.18 may be combined with any single analgesic-antipyretic active ingredients or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or aspirin and antacid combinations.

(n) Any single oral nasal decongestant active ingredient identified in § 341.20(a) may be combined with any single analgesic-antipyretic active ingredients or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or aspirin and antacid combinations.

(o) Any single oral nasal decongestant active ingredient identified in § 341.20(a) may be combined with any single expectorant active ingredient identified in § 341.18.

(p) Any single oral nasal decongestant active ingredient identified in § 341.20(a) may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.10 of this chapter provided that the product is available in a solid dosage form to be dissolved in the mouth and swallowed.

(q) Any single oral nasal decongestant active ingredient identified in § 341.20(a) may be combined with any single oral antitussive active ingredient identified in § 341.14(a) and any single anesthetic/analgesic active ingredient identified in § 356.10 of this chapter provided that the product is available in a solid dosage form to be dissolved in the mouth and swallowed.

(r) Camphor identified in § 341.14(b)(1) may be combined with menthol identified in § 341.14(b)(2) and eucalyptus oil (1.2 to 1.3 percent) provided that the product is available only in a suitable ointment vehicle.

(s) 1-desoxyephedrine identified in § 341.20(b)(1) may be combined with aromatics (camphor (54 mg), menthol (80 mg), methyl salicylate (11 mg), bornyl acetate (0.2 mg), and lavender oil (4 mg)) provided that the product is available only as an inhaler.

(t) Promethazine hydrochloride identified as an antihistamine (if labeled for relief of symptoms of the common cold as identified in § 341.72(b)(2)) may be used in combination with other cough-cold and/or analgesic-antipyretic ingredients as provided for antihistamine active ingredients in § 341.40 (a) through (f) of this section.

(u) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral demulcent active ingredient identified in § 356.18 of this chapter provided that the product is in a solid dosage form to be dissolved in the mouth and swallowed.

(v) Any single oral nasal decongestant active ingredient identified in § 341.20(a) may be combined with any single oral demulcent active ingredient identified in § 356.18 of this chapter provided that the

product is in a solid dosage form to be dissolved in the mouth and swallowed.

(w) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any single oral demulcent active ingredient identified in § 356.18 of this chapter provided that the product is in a solid dosage form to be dissolved in the mouth and swallowed.

(x) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.10 of this chapter and any single oral demulcent active ingredient identified in § 356.18 of this chapter provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed.

(y) Any single oral nasal decongestant active ingredient identified in § 341.20(a) may be combined with any single oral anesthetic/analgesic active ingredient identified in § 356.10 of this chapter and any single oral demulcent active ingredient identified in § 356.18 of this chapter provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed.

(z) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any single oral anesthetic/analgesic active ingredient identified in § 356.10 of this chapter and any single oral demulcent active ingredient identified in § 356.18 of this chapter provided that the product is available only in a solid dosage form to be dissolved in the mouth and swallowed.

3. In Subpart C, new § 341.85 is added to read as follows:

§ 341.85 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (a).

(1) *For permitted combinations identified in § 341.40 (a), (c), (f), (k), (m), and (n) containing an analgesic-antipyretic active ingredient.* The analgesic-antipyretic component of the product shall be identified as a "pain reliever" or "analgesic (pain reliever)." If the product is also labeled to relieve fever, then the analgesic-antipyretic component is identified as a "pain reliever-fever reducer" or "analgesic (pain reliever)-antipyretic (fever reducer)."

(2) [Reserved]

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in the applicable OTC drug monographs or listed in this paragraph, may also be used, as provided in § 330.1(d)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For permitted combinations containing an analgesic-antipyretic active ingredient identified in § 341.40 (a), (c), (f), (k), (m), and (n) when labeled for relief of cough-cold symptoms.* The following indication for analgesic-antipyretic ingredients should be used. "For the temporary relief of minor aches, pains, headache, muscular aches, and fever associated with" (select one of the following: "the common cold" or "a cold") (followed by the appropriate indication(s) for the cough-cold ingredient(s).)

(2) *For permitted combinations containing an analgesic-antipyretic active ingredient identified in § 341.40 (a), (c), and (n) when labeled for relief of hay fever/allergic rhinitis and/or sinusitis symptoms.* The following indication for analgesic-antipyretic ingredients should be used. "For the temporary relief of minor aches, pains, and headache" (followed by the labeling for antihistamines in § 341.72(b)(1) and/or the labeling for nasal decongestants in § 341.80(b)(1) (ii) or (iii), as appropriate).

(3) *For permitted combinations containing an analgesic-antipyretic active ingredient identified in § 341.40 (a), (c), and (n) when labeled for relief of cough-cold symptoms and for relief of hay fever/allergic rhinitis and/or sinusitis symptoms.* Both indications in § 341.85(b) (1) and (2) must be used.

(4) *For permitted combinations containing an anesthetic-analgesic active ingredient identified in § 341.40 (j), (p), (q).* The indication for anesthetic/analgesics in § 356.55(b)(1) of this chapter should be used.

(5) *For permitted combinations containing the antihistamine promethazine hydrochloride identified in § 341.40(t).* The indication for antihistamines in § 341.72(b)(2) should be used.

(6) *For permitted combinations containing 1-desoxyephedrine and aromatics (camphor, menthol, methyl salicylate, bornyl acetate, and lavender oil) as a topical nasal decongestant administered by a nasal inhaler.* The indications for nasal decongestants in § 341.80(b) should be used.

(7) *For permitted combinations containing menthol, camphor, and eucalyptus oil as topical antitussives in an ointment.* The indication for antitussives in § 341.74(b) should be used.

(8) *Other allowable statements.* In addition to the required information identified in this section (b), the labeling of the combination drug product may contain any of the "other allowable statements" (if any), that are identified in the applicable monographs, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (c). [All citations that refer to § 343.50 of this chapter will be published in a future issue of the **Federal Register**.]

(1) *For permitted combinations containing an antitussive and an analgesic-antipyretic identified in § 341.40 (f) and (k).* The following products are to be labeled, accordingly.

(i) *For products labeled for adults.* The following warning should be used instead of the warnings in § 343.50(c)(1)(i) of this chapter and

§ 341.74(c)(1)(ii). "Do not take this product for more than 10 days. A persistent cough may be a sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by rash, persistent headache, fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

(ii) *For products labeled for children under 12 years of age.* The following warning should be used instead of the warnings in § 343.50(c)(2)(i) of this chapter and § 341.74(c)(2)(ii). "Do not give this product to children for more than 5 days. A persistent cough may be a sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by rash, persistent headache, fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

(iii) *For products labeled for both adults and for children under 12 years of age.* The following warning should be used instead of the warnings in § 343.50(c)(3) of this chapter and §§ 341.74 (c)(1)(ii) and (c)(2)(ii). "Do not take this product for more than 10 days (for adults) or 5 days (for children). A persistent cough may be a sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by rash, persistent headache, fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

(2) *For permitted combinations containing an expectorant and an analgesic-antipyretic identified in § 341.40(m).* The following products are to be labeled, accordingly.

(i) *For products labeled for adults.* The following warning should be used instead of the warnings in § 343.50(c)(1)(i) of this chapter and § 341.78(c)(3). "Do not take this product for more than 10 days. A persistent cough may be a sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by rash, persistent headache, fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

(ii) *For products labeled for children under 12 years of age.* The following warning should be used instead of the warnings in § 343.50(c)(2)(i) of this chapter and § 341.78(c)(3). "Do not give this product to children for more than 5 days. A persistent cough may be a sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by rash, persistent headache, fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

(iii) *For products labeled for both adults and for children under 12 years of age.* The following warning should be used instead of the warnings in § 343.50(c)(3) of this chapter and § 341.78(c)(3). "Do not take this product for more than 10 days (for adults) or 5 days (for children). A persistent cough may be a sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by rash, persistent headache, fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

(3) *For permitted combinations containing a nasal decongestant and an analgesic-antipyretic identified in § 341.40 (c), (f), (k), and (n).* The following products are to be labeled, accordingly.

(i) *For products labeled for adults.* The following warning should be used instead of the warnings in § 343.50(c)(1)(i) of this chapter and § 341.80(c)(1)(i)(b). "Do not take this product for more than 10 days. If symptoms do not improve or are accompanied by fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

(ii) *For products labeled for children under 12 years of age.* The following warning should be used instead of the warnings in § 343.50(c)(2)(i) of this chapter and § 341.80(c)(1)(ii)(b). "Do not give this product to children for more than 5 days. If symptoms do not improve or are accompanied by fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

(iii) *For products labeled for both adults and children under 12 years of age.* The following warning should be used instead of the warnings in § 343.50(c)(3) of this chapter and § 341.80(c)(iii). "Do not take this product for more than 10 days (for adults) or 5 days (for children). If symptoms do not improve or are accompanied by fever that lasts for more than 3 days, or if new symptoms occur, consult a doctor."

(4) *For permitted combinations containing promethazine hydrochloride identified in § 341.40(t).* The following products are to be labeled, accordingly.

(i) *For products labeled for adults.* The warnings for antihistamines in § 341.72(c) (1) and (4) must be used, in addition to the following: "Do not take this product if you have asthma, glaucoma, emphysema, liver disease, seizures, chronic pulmonary disease, shortness of breath, difficulty in breathing, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(ii) *For products labeled for children under 12 years of age.* The warnings for antihistamines in § 341.72(c)(1) and (6)(iii) must be used, in addition to the following: "Do not give this product to children who have asthma, liver disease, seizures, or glaucoma unless directed by a doctor."

(5) *For combination drug products containing an antihistamine combined with an oral antitussive.* The warning "May cause marked drowsiness," must be used. The word "marked" may be deleted from the warning upon petition under the provisions of § 10.30 of this chapter provided adequate data are submitted to demonstrate that the combination product does not cause a significant increase in drowsiness as compared with each active ingredient when tested alone. The petition and the data it contains will be maintained in a permanent file for public review by the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

(6) *For combination drug products containing 1-desoxyephedrine and aromatics (camphor, menthol, methyl salicylate, bornyl acetate, and lavender oil) as a topical nasal decongestant administered by a nasal inhaler.* The warnings for topical nasal decongestants in § 341.80(c) must be used.

(7) *For combination drug products containing menthol, camphor, and eucalyptus oil as topical antitussives in an ointment.* The warnings for topical antitussives in § 341.74(c) must be used.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

(1) *For permitted combinations containing promethazine hydrochloride identified in 341.40(t).* Adults and children 12 years of age and older: oral dosage is 6.25 milligrams every 4 to 6 hours, not to exceed 37.5 milligrams in 24 hours. Children 6 to under 12 years of age: Oral dosage is 3.125 milligrams every 4 to 6 hours, not to exceed 18.75 milligrams in 24 hours. Children under 6 years of age: Consult a doctor.

(2) [Reserved]

(e) *Optional wording.* The word "physician" may be substituted for the

word "doctor" in any of the labeling statements in this section.

4. In § 341.90, new paragraph (r) is added to read as follows:

§ 341.90 Professional labeling.

* * * * *

(r) *For permitted combinations containing promethazine hydrochloride as identified in § 341.40(t).* Children 2 to under 6 years of age: Oral dosage is 1.56 milligrams every 4 to 6 hours, not to exceed 9.36 milligrams in 24 hours.

Dated: May 2, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88-18066 Filed 8-11-88; 8:45 am]

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Friday
August 12, 1988

Part III

Environmental Protection Agency

40 CFR Part 82

Protection of Stratospheric Ozone; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[OAR-FRL-3409-7]

Protection of Stratospheric Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule limits the production and consumption of certain chlorofluorocarbons (CFCs) and brominated compounds (halons) to reduce the risks of stratospheric ozone depletion. It requires a near-term freeze at 1986 levels of production and consumption (defined as production plus imports minus exports) of CFC-11, -12, -113, -114, and -115 based on their relative ozone depletion weights, followed by a phased reduction to 80 percent and 50 percent of 1986 levels beginning in mid-1993 and mid-1998, respectively. It also limits production and consumption of Halon 1211, 1301, and 2402 to 1986 levels beginning as early as 1992. Under specified circumstances, limited increases in production (but not consumption) above these levels would be permitted.

Promulgation of this rule is authorized by section 157(b) of the Clean Air Act and constitutes the United States' implementation of the "Montreal Protocol on Substances that Deplete the Ozone Layer" (Montreal Protocol), which the United States ratified on April 21, 1988. The final rule's control measures will take effect when the Protocol enters into force, which could occur as early as January 1, 1989.

The rule implements the Protocol's requirements to control production and consumption of the CFCs and halons specified above by allocating production and consumption allowances to firms that produced and imported these chemicals in 1986, based on their 1986 levels of these activities. By directly restricting the supply of the regulated chemicals, the United States will meet its obligations under the Montreal Protocol by means of a straightforward, economically efficient, and easily administered regulatory program.

In a separate notice appearing elsewhere in today's **Federal Register**, EPA is seeking public comment on an advance notice of proposed rulemaking (ANPRM) which discusses supplementing this final rule with a regulatory fee and/or engineering controls or bans on specific uses of CFCs and halons or replacing allocated quotas with an auction system.

Ideally, market based systems are preferable. An auction, in particular, would insure compliance with the Protocol, and would shift some windfalls from the producers to the United States Treasury. EPA is not adopting an auction of production and consumption allowances at this time due to remaining legal and economic concerns. After reviewing the public comment, the Agency will decide whether to propose a rule supplementing the allocated quota system or shifting to an auction approach, and depending on its decision, would issue a notice of proposed rulemaking containing a detailed description of any proposed modification.

The ANPRM also discusses scientific information now available in summary form that could not be considered in this rulemaking but which suggests that the risks of ozone depletion may be greater than previously anticipated.

EFFECTIVE DATE: This final rule will take effect upon entry into force of the Montreal Protocol. The United States and other Parties to the Protocol will likely have 90 days prior notice of the date on which the Protocol will enter into force. When EPA learns of that date, it will publish a document in the **Federal Register** announcing the effective date of this rule and the dates of each of the rule's control periods. The reporting requirements in § 82.13(f)(1) of the rule takes effect September 12, 1988.

ADDRESS: Comments and other information relevant to this rulemaking (Docket No. A-87-20) may be viewed at the Central Docket Section, South Conference Room 4, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. The docket may be inspected between 8:00 a.m. and 3:30 p.m. on weekdays. As provided in 40 CFR Part 2, a reasonable fee may be charged for photocopying.

FOR FURTHER INFORMATION CONTACT: Stephen Seidel, Senior Analyst, Office of Program Development, Office of Air and Radiation (ANR-445), EPA, 401 M Street, SW., Washington, DC 20460. Telephone (202) 382-2787.

SUPPLEMENTARY INFORMATION:

I. Background

Stratospheric ozone shields the earth's surface from dangerous ultraviolet (UV-B) radiation. In response to growing scientific evidence, a national and international consensus has developed that unabated use of CFCs and halons will result in depletion of stratospheric ozone. To the extent depletion occurs, penetration of UV-B radiation will increase, resulting in potential health and environmental harm including increased incidence of certain skin cancers and cataracts, suppression of the immune response system, damage to crops and aquatic organisms, increased formation of ground-level ozone, and increased weathering of outdoor plastics.

EPA evaluated the risks of ozone depletion and published its findings in "Assessing the Risks of Trace Gases That Can Modify the Stratosphere" (EPA, 1987), which the Agency's Science Advisory Board (SAB) reviewed and approved.

Based on the Agency's risk assessment work, the Administrator concluded that an international approach was necessary to effectively safeguard the ozone layer. As EPA pointed out in its December 14, 1987 proposal (52 FR 47489), theory and available scientific evidence make clear that the problem of stratospheric ozone depletion is global in nature. Over their long atmospheric lifetimes, CFCs and halons become widely dispersed, and the release of these chemicals in one country adversely affects the stratosphere above, and therefore the health and welfare of, other countries. The United States currently contributes about 30 percent of worldwide CFC emissions, and its percentage contribution will probably decrease as developing countries increase their consumption of CFCs and halons, which are used primarily in refrigeration, foam-blowing, electronics production, and fire-fighting. As a result, EPA sought to further negotiation of a protocol requiring all nations to curb their use of these chemicals.

After a series of international workshops on the cause and effects of ozone depletion, negotiations for an international control protocol resumed in December 1986. Last September the United States and 23 other nations signed the Montreal Protocol and since then 13 more have signed. The United States, Mexico, Norway, Sweden, Canada, and New Zealand have ratified the Protocol, and several other nations (e.g., Japan, Western European nations) are close to ratifying the agreement, as well.

A. The Montreal Protocol

Briefly, the Montreal Protocol requires nations who join to restrict their production and consumption of CFC-11, -12, -113, -114, -115 and Halons 1211, 1301, and 2402 in bulk form (referred to as "controlled substances"). It does not place limits on each of the controlled substances, but instead groups the CFCs together (Group I) and the halons together (Group II) and places separate

limits on the total ozone depletion potential of each group of controlled substances that can be produced and consumed. As a result, within each group the mix of controlled substances a nation produces and consumes may change, so long as the total ozone depletion potential of the mix does not exceed the specified limits. The Protocol uses the phrase "calculated level" to refer to this weighting of controlled substances based on their relative ozone depletion potential.

The Protocol calls for a phased reduction in the production and consumption of Group I controlled substances and a freeze in the production and consumption of Group II controlled substances. Specifically, Group I substances are frozen at 1986 levels beginning on July 1, 1989, assuming the Protocol enters into force on January 1, 1989. (The Protocol will enter into force on that date if 11 nations or regional economic integration organizations have ratified the Protocol. Otherwise, the Protocol will take effect 90 days after these conditions have been met.) Group I substances are then reduced to 80 percent and 50 percent of 1986 levels by July 1, 1993, and July 1, 1998, respectively. Group II controlled substances are frozen at 1986 levels beginning on January 1, 1992, assuming the Protocol enters into force on January 1, 1989.

The Protocol also allows for limited increases in production beyond the reductions described above under prescribed circumstances. In addition, it also bans imports of controlled substances from nations which neither join nor comply with the Protocol one year after the Protocol enters into force. (The text of the Protocol is described in detail and printed in its entirety in the December 14, 1987 notice of proposed rulemaking (NPRM).)

B. December 14, 1987 Proposal

In the December 14, 1987 NPRM, the Agency proposed regulations that would ensure United States' compliance with the Montreal Protocol. EPA stated that based on its assessment of the available evidence, the Protocol's requirements are an appropriate response to the potential ozone depletion problem at this time. The Agency estimated that compliance with the Protocol by most developed and developing nations would reduce ozone depletion by the year 2075 to 1.3 percent, and stated that given the many variables and uncertainties involved in predicting ozone depletion far into the future, the Protocol would achieve a reasonable degree of risk reduction. Because of the need for an international solution to the ozone depletion problem, EPA added that it would be unwise to risk undermining the agreement by deviating from its requirements.

EPA proposed to implement fully the Protocol's control requirements and import ban. It proposed to adopt the Protocol's definition of "controlled substances" and its application of limits on CFCs as a group and halons as a group on a ozone depletion potential basis ("calculated level"). It also provided for increases in production of controlled substances over the otherwise applicable limits consistent with the Protocol's allowances for such increases. In addition, the Agency proposed that the regulations take effect when the Protocol enters into force.

The December 14 NPRM set forth a number of control strategies for domestically implementing the terms of the Protocol. EPA stated that its preferred control strategy was an "allocated quota" system. Under this approach, EPA would grant production and consumption "rights" or privileges equal to the quantity of production and consumption allowed under the Protocol. These rights would be apportioned to producers and importers of controlled substances based on their 1986 levels of production and imports, and would be frozen and reduced according to the schedule specified in the Protocol. In effect, this proposal would grandfather in past producers and importers at their 1986 relative market shares. EPA also proposed that rights be transferable, so that firms could buy and sell production and consumption rights and thus respond to changing market conditions.

According to economic theory, an allocated quota system should achieve EPA's regulatory goal at the lowest possible cost to society. By restricting the supply of CFCs and halons, this system should cause the price of these chemicals to be bid up over time by firms seeking to purchase them. The resulting price increases should, in turn, encourage firms to reduce their use of these chemicals and to increase recycling and recovery, and should also create a market incentive for the introduction of chemical substitutes. A declining supply of CFCs and halons would continue to be available, though at a higher price, to the highest value users of these chemicals.

While EPA proposed the allocated quota system, it also identified and sought comment on the potential implications of the "windfall profits" that would accrue primarily to the five domestic CFC producers as a result of the system driving up the price of these chemicals. The Agency also noted for public comment the potential need to augment this system with direct regulation of key user groups to ensure that low-cost reductions were undertaken as soon as they become cost-effective (termed the hybrid option in the December 14 NPRM).

EPA presented and sought comment on several other regulatory approaches. As an alternative to allocating rights to past producers and importers, the NPRM discussed the possibility of auctioning rights to the highest bidder. The price paid at auction for the rights would reflect the expected higher market price for the controlled substances and any such increase would be paid to the United States Treasury instead of the producers. However, EPA raised concerns about the large uncertainties bidders would likely face during the early stages of an auction and the potential impact of participation by large users or speculators.

A third option presented by EPA involved the use of a regulatory fee. Under this option, CFC and halon production would be assessed a fee set at a level sufficient to raise prices that would in turn reduce demand to the requisite level. Like auctions, this approach would result in price increases from controlled substances (i.e., the transfers) going to the United States Treasury. However, because of the uncertainties in determining the level of a fee necessary to achieve a desired reduction, the NPRM pointed out that use of a fee by itself would make it difficult to ensure United States' compliance with the Montreal Protocol.

In contrast to the above options which all rely on economic incentives, EPA also discussed the possibility of employing the Agency's traditional regulatory approach—industry-specific control requirements. Under this approach, EPA would target and require controls on specific uses of CFCs and halons. However, as with regulatory fees, use of this option by itself would not ensure that the United States would meet the Protocol's control requirements (e.g., growth in unregulated uses could offset reductions from required controls).

On January 7 and 8, 1988, EPA held a public hearing in Washington, DC, to receive oral testimony on the NPRM. Approximately 25 witnesses representing producer and user industries, the scientific community, and public interest groups presented testimony at the hearing. A transcript of the hearing is contained in the public docket.

The public comment period on the December proposal closed on February 8, 1988. EPA received almost 500 comments including submissions by the major CFC and halon producers, most of the trade associations and large companies in industries which use these chemicals, interested citizens, other federal agencies, and public interest groups. Because of the volume of these comments, EPA has prepared and placed in the docket a separate document, "Background Information Document: Stratospheric Ozone Protection Rulemaking," which describes and responds to each of the significant issues raised in the public comments. This document is incorporated by reference in this notice. In addition, throughout this preamble, key issues raised in the public comments are identified and EPA's response provided, along with any changes in the final rule which may have resulted.

C. December 14, 1987 Final Rule

In addition to its NPRM, EPA also published in the **Federal Register** on December 14, 1987 a final rule (40 CFR 82.20; 52 FR 47486) requiring firms to document and report to EPA the amount of controlled substances they had produced, imported and/or exported in 1986. EPA needed this data to provide the United Nations Environment Program (UNEP) with a preliminary estimate of the United States' 1986 consumption and production of controlled substances and to develop company-specific apportionments of production and consumption rights.

D. May 24, 1988 Supplementary Proposal

On May 24, 1988, EPA issued a supplemental proposal which set forth company-specific apportionments of production and consumption rights (53 FR 18800). It also addressed issues raised by responses to the December 14 proposed and final rules relating to the apportionment of rights and implementation of the proposed rule. These issues and EPA's final resolution of them in light of the May supplemental proposal are described in later sections of this preamble.

II. Statutory Authority and Applicable Legal Test

A. Statutory Authority

EPA is promulgating this final rule under section 157(b) of the Clean Air Act, 42 U.S.C. 7457(b). That section authorizes the Administrator to issue "regulations for the control of any substance, practice, process, or activity [or any combination thereof] which in his judgment may reasonably be anticipated to affect the stratosphere, especially ozone in the stratosphere, if such effect in the stratosphere may reasonably be anticipated to endanger public health or welfare. Such regulations shall take into account the feasibility and the costs of achieving such control."

As the Agency pointed out in its December 14 NPRM, two aspects of this regulatory authority are notable. First, the Administrator is not required to prove that a "substance, practice, process or activity" does in fact deplete stratospheric ozone before he may regulate it. Congress recognized the potentially serious health and environmental consequences of ozone depletion if it were occurring, and authorized EPA to act in the face of scientific uncertainty. Second, the Administrator is given broad latitude to choose what and how to regulate. He is not limited to controlling ozone-depleting substances themselves; he may also regulate "any practice, process, activity" that threatens the ozone layer. Nor is he limited to a particular control strategy. He may employ the regulatory options he finds appropriate to control threats to stratospheric ozone that in turn threaten public health and welfare.

B. Applicable Legal Test

Commenters on the Agency's proposal agreed that section 157(b) authorizes EPA to promulgate regulations to protect stratospheric ozone as needed to protect public health and welfare. However, several environmental groups disagreed with EPA's judgment that implementation of the Montreal Protocol will satisfy that section. They argued that EPA is obligated to require further, faster reductions in CFCs and halons based on evidence that the Agency expressly found insufficient as a basis for taking regulatory action at this time. They also asserted that EPA is obligated to take unilateral action as needed to protect stratospheric ozone, and cannot make its regulations contingent on an international agreement taking effect.

At the heart of these commenters' argument is an interpretation of section 157(b) that obligates EPA to protect against all "potential" dangers involving stratospheric ozone. They find this obligation in the section's provision for controls of virtually anything "which in [the Administrator's] judgment *may reasonably be anticipated to affect* the stratosphere, * * * if such effect * * * *may reasonably be anticipated to endanger* public health or welfare" (emphasis added). The "reasonably anticipated" language, they contend, requires EPA to act when there is potential danger, not just when danger is certain. Moreover, when a global resource like stratospheric ozone is at stake, they assert that the Act requires EPA to regulate to protect the resource even if there is more uncertainty than is considered tolerable regarding more limited dangers.

EPA agrees that section 157(b) takes a precautionary approach to protecting stratospheric ozone. Both its language and legislative history make clear that EPA is authorized to regulate before harm occurs and, optimally, to prevent harm. However, EPA does not agree that section 157(b) requires the Agency to prevent all potential harm. "Reasonably anticipated" harm connotes a likely harm or a harm whose likelihood and magnitude together are large enough to make preventive measures reasonable. Put another way, section 157(b) authorizes EPA to assess the risks of stratospheric ozone depletion and to regulate as the assessment warrants.

The legislative history of section 157(b) confirms that Congress intended the Agency to assess risks and regulate on that basis. The "reasonably anticipated" language was crafted against the backdrop of recent DC Circuit opinions in *Ethyl Corporation v. EPA* on the Agency's authority under the 1970 Clean Air Act to reduce the lead in gasoline. A three judge panel had held that EPA must prove that lead in gasoline by itself caused significant harm, notwithstanding the likely impossibility of making that case before the harm actually occurred. The panel's decision was later reversed by the court *en banc* (541 F.2d 1 (1976)), which found that the Act authorized EPA to act before harm occurred based on its assessment of risk.

Congress, in revising the Act, sought to codify the *en banc* panel's decision. The House Committee which drafted section 157(b) stated in its report that it had used "a standardized basis for future rulemaking to protect the public health: the Administrator may regulate a pollutant, emissions of 'which in his judgment cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare.' " It explained that the purpose of this standardized basis was, among other things, to "authorize the Administrator to weigh risks and make reasonable projections of future trends," and "to reflect awareness of uncertainties and limitations in the data which will be available to the Administrator in the foreseeable future * * *"

The committee also included the words "in [the Administrator's] judgment" in the foregoing phrase "to emphasize the necessarily judgmental element in the task of predicting future health risks of present action and to confer upon the Administrator the requisite authority to exercise such judgment." Specifically in reference to section 157(b), the committee quoted with approval another committee's statement that "the phrase 'may reasonably be anticipated' is intended to give the Administrator discretion in proposing and promulgating regulations."

Congress, however, did not authorize EPA to assess risks based on a "crystal ball" inquiry. The House Committee report indicates that Congress expected EPA's risk assessments to be based on evidence that had been adequately adduced (e.g., measured against any critical comments) and rationally applied. Again in reference to section 157(b), the Committee adopted another committee's explanation that the Administrator should rely on reputable scientific data that, while not immune from challenge, must be reasonably reliable.

EPA therefore reads section 157(b) as authorizing regulation to reduce or eliminate risks that the Agency considers will "endanger" health based on available, reliable evidence. Whether or not a risk warrants a regulatory response depends on the likelihood of the harm occurring and the magnitude of the harm that would occur; for example, the risk of an improbable, but potentially far-reaching harm may still warrant reduction or elimination. Obviously, the characterization of a risk entails the exercise of judgment, and the statute makes clear that the Administrator is authorized to exercise such judgment.

EPA also believes that in deciding whether and how to regulate under section 157(b) it may consider other countries' effect on stratospheric ozone and the effect of United States action on other countries' willingness to take regulatory action. There is no dispute that the cause and effects of ozone depletion are global in nature. Ozone-depleting emissions from all nations mix in the atmosphere and threaten the stratosphere above every nation. Thus, in order to assess the risk of ozone depletion and the need for regulatory action, EPA must consider other nations' actions affecting the stratosphere. A logical next step in this analysis is what effect United States action could have on other nations' actions now and in the future.

Consideration of the international ramifications of United States action is also appropriate in analyzing the cost and feasibility of controls, as required by section 157(b). The legislative history of that section indicates that Congress expected the Agency to use the cost and feasibility analysis to determine the most appropriate means of protecting the stratosphere. Certainly other nations' ozone-depleting emissions or control of emissions affect the cost of United States' controls, and the need for other nations to limit their emissions may make appropriate United States action that encourages, or does not discourage, other nations to agree to such limits.

A recent DC Circuit case confirms that EPA may consider potential international ramifications in making a regulatory decision, where, as here, those ramifications are relevant to achieving the statutory purpose. In *National Coalition Against the Misuse of Pesticides* v. *Thomas*, 815 F. 2d 1579 (DC Cir. 1987), the court upheld the Agency's decision to extend the period of time imported mangoes could be treated with a particular pesticide because a contrary decision could have jeopardized mango-producing nations' willingness to find and use a safer alternative. The relevant statutory purpose was to ensure the safety of the United States food supply; and the court found that the Agency reasonably concluded that loss of other nations' cooperation in that endeavor posed a greater risk to the food supply than short-term use of the pesticide.

III. Risk Assessment

As noted above, EPA prepared an assessment of the risks of stratospheric ozone depletion to provide a basis both for United States' participation in negotiation of an international control protocol and for a regulatory decision on the need for future domestic control of ozone-depleting substances (EPA, 1987). The risk assessment was reviewed in draft form by an SAB subcommittee made up of independent experts in the disciplines relevant to predicting ozone depletion and its effects. At the same time, the draft assessment was made available for public comment. Based on comments from the subcommittee, its individual members, and the public, EPA revised the risk assessment and submitted the revised version to the SAB subcommittee for further review. In its closure letter of January 29, 1988, the head of the Subcommittee stated that the final assessment "adequately responded to the Subcommittee's advice on all major scientific issues".

EPA used the risk assessment as the basis for its regulatory impact analysis (RIA) and proposed rule. These documents examine in detail: Past and future trends in trace gases that affect ozone levels; measurements of atmospheric levels of ozone; estimates of future changes in ozone levels derived from atmospheric models; and health and environmental effects that would be associated with depletion of the ozone layer.

A. Past and Future Changes in Atmospheric Composition

As the Agency explained in its December 14 NPRM, measurements taken over the past several decades of the chemical composition of the earth's atmosphere have demonstrated that human activities are altering its make-up. In particular, the atmospheric concentrations of CFCs and halons, which destroy stratospheric ozone, have been increasing. For example, the atmospheric concentrations of CFC-11 and -12 have been increasing at an annual rate of 5 percent during the past decade (WMO, 1986). Other gases which act to slow or offset the destruction of ozone have also been increasing. For example, carbon dioxide levels have increased by 25 percent since the beginning of the industrial revolution (WMO, 1986), and methane concentrations have increased at an annual rate of .017 parts per million during the past decade (EPA, 1987).

Future changes in atmospheric concentrations of these gases will determine the net impact on the ozone layer. As part of its risk assessment, EPA developed scenarios for future trends in the growth of these gases. These scenarios were also used in the RIA prepared in support of this rule.

The scenario used in the RIA to characterize what would happen absent controls ("the baseline") assumed the following growth rates:

TABLE 1.—PROJECTED GLOBAL GROWTH RATES FOR OZONE-MODIFYING COMPOUNDS [1]

	1986-1992	1992-2000	2000-2050	2050-2075
CFC-11	4.34	2.71	2.50	0.00
CFC-12	5.32	3.06	2.50	0.00
CFC-113	7.03	4.09	2.50	0.00
CFC 114	4.95	2.79	2.50	0.00
CFC-115	3.20	2.73	2.50	0.00
Halon 1211	9.77	4.80	2.93	0.00
Halon 1301	3.46	2.20	3.16	0.00
HCFC-22	4.37	2.74	2.50	0.00
Methyl Chloroform	4.70	2.78	2.50	0.00
Carbon Tetrachloride	4.90	2.91	2.50	0.00
Carbon dioxide			0.5%/yr	
Nitrous oxide			0.2%/yr	
Methane	(2)	(2)	(2)	(2)

[1] Average annual rates computed using data cited in Exhibit 4-5 of the RIA. Rates vary for developed and developing nations and by region.
[2] 0.017 parts per million/year.

See chapter 4 of the RIA for a more detailed breakdown of growth rates.

These growth rates are similar to those contained in the December 14 NPRM, but reflect higher CFC growth for 1987 based on actual data (CFC-11 and -12 grew by 13 percent instead of the less than 3 percent EPA had assumed) and a slightly higher growth rate for CFC-11 and -12 through 1992 in the baseline case to more accurately reflect the recent period of sustained high growth in these chemicals—U.S. production of CFC-11 and CFC-12 has grown by 24 percent since 1985.

Several chemical producers and organizations criticized EPA's baseline trace gas scenario. One stated that the Agency's choice of 0.017 parts per million annual growth rate for methane and 0.2 annual percent growth rate for nitrous oxide concentrations differed from the standard assumptions generally used by atmospheric modelers and that they had not been reviewed by the SAB subcommittee. Others criticized EPA's projection of sustained growth for methyl chloroform and HCFC-22 as being unrealistic. Several public interest groups objected that EPA did not assume future controls on carbon dioxide and methane which slow the rate of ozone depletion but also contribute to global warming. They argued that the potentially catastrophic effects of global warming made EPA's assumption of continued uncontrolled growth of greenhouse gases unreasonable.

EPA believes that its baseline trace gas scenario represents appropriate assumptions based on the best available scientific information. In the case of methane, the Agency's choice of a growth rate for changes in atmospheric concentrations is based on a survey of the research groups involved in methane measurements. Moreover, a methane growth rate almost used identical to that by EPA was recently described as "the best current description of growth in CH_4 concentrations" in an article on methane published after the completion of the risk assessment. (Blake, 1988). EPA's choice of a growth rate for nitrous oxide is also fully consistent with the available scientific literature. Contrary to the assertion of one commenter, these baseline trace gas growth rate assumptions were included in the second draft of EPA's risk assessment summary that the SAB subcommittee reviewed and approved, and in any event fall well within the range of assumptions approved by the subcommittee both in the assessment's draft and final forms. Finally, recognizing the uncertainties inherent in making long term projections, EPA included in the RIA sensitivity analyses which examine the impact on predicted ozone depletion of alternative trace gas scenarios. These analyses indicate that none of the RIA's conclusions would be significantly modified by changing these trace gases assumptions along the lines suggested by the commenters.

EPA also believes that the growth rates assumed in its scenarios for HCFC-22 and methyl chloroform are reasonable. These chemicals continue to be widely used in the United States and their use abroad has been expanding and is likely to continue to increase over time. To the extent these chemicals may be substituted for CFCs in the future, the EPA baseline scenarios may actually underestimate future growth in these chemicals.

EPA does not believe it appropriate to assume at this time in its baseline case that controls will be imposed on greenhouse gases. Commenters who argue that EPA must assume controls misconstrue the reason behind the Agency's assumption of continued growth of greenhouse gases. The purpose of the rulemaking is to promulgate controls needed to protect stratospheric ozone. In assessing what controls are needed, the Agency has taken the world as it is; since no action has yet been instituted to limit greenhouse gases, the Agency assumes no controls on these gases in its baseline case. Moreover, until action is instituted, EPA has no reliable basis for predicting the timing or stringency of future controls.

However, because of the Agency's concern about the potential impact of continued growth in greenhouse gas emissions, EPA did examine as part of its sensitivity analysis in the RIA the impact of limiting growth in carbon dioxide and methane. The analysis shows that in the absence of controls on any of the relevant trace gases, the EPA baseline scenario would result in a global equilibrium temperature increase of 6.0 degrees centigrade by 2075. The scenario reflecting the reductions in CFCs and halons required by the Montreal Protocol would reduce the projected global warming equilibrium temperature to 4.3 degrees centigrade by 2075. Because methane and carbon dioxide act to increase ozone, if controls are placed on them to limit global warming to an equilibrium warming of 2.0 degrees centigrade by 2075, the resulting effect would be to increase ozone depletion by the date from under 2 percent (in the case of implementing the Montreal Protocol) to around 6 percent. While a consideration of potential global warming is outside the scope of this rulemaking, EPA recognizes that because the same trace gases govern both climate change and ozone depletion, these issues are closely connected. Should future steps be taken to address global warming, the Agency will consider the need to revise its CFC and halon control requirements to ensure that the stratospheric ozone layer is maintained.

Seven chemical producers and users stated that EPA's baseline and other

scenarios incorrectly assumed that CFC and halon use would grow unabated in the future despite evidence of ozone depletion (i.e., firms would voluntarily reduce CFC and halon use). EPA's assumption concerning baseline growth of CFCs and halons was the product of several years of analysis and review including many different studies undertaken both here and abroad. (For a summary of these studies, see chapter 4 of the RIA). The goal of these studies was to project demand for these chemicals in the absence of regulation. Given the long time period covered by these projections (typically many decades to over a century, the atmospheric lifetimes of CFCs and halons), considerable uncertainty in the estimates is unavoidable. Nonetheless, the studies demonstrate that in the absence of regulation substantial sustained growth in demand for CFCs and halons would be likely.

The notion that firms would shift away from CFCs and halons in the face of evidence of ozone depletion is flawed for two reasons. First, it does not comport with recent history. Despite the fact that over the past two years public concern and scientific evidence about the threat of ozone depletion has grown, use of these chemicals has surged by an annual average of 11.5 percent rather than slackened. Second, it misunderstands the role of the baseline in a regulatory analysis. The baseline serves as the basis for estimating costs of shifting away from harmful chemicals. If EPA decided not to regulate CFCs and halons and the ozone layer thinned, some firms indeed might reduce their use voluntarily or in response to public pressure. However, because section 157(b) requires EPA to consider total costs of protecting the ozone layer, EPA appropriately considered all costs to society, including the cost incurred by firms in shifting away from CFCs and halons either in response to regulation or as a voluntary action.

B. Past and Future Changes in Ozone Levels

Measurements of changes in atmospheric concentrations of ozone-modifying gases provide only indirect evidence that human activities may be altering the ozone layer. Two other methods for analyzing the risk of ozone depletion are direct measurement of ozone to detect any trends and use of atmospheric models to project future ozone trends based on assumed changes in atmospheric levels of ozone-modifying gases.

1. Direct Measurements of Ozone Levels

In the preamble to the December 14 proposal, EPA described the extent and significance of available satellite and ground-based measurements of ozone. The Agency cited the 1986 World Meteorological Organization (WMO) assessment which concluded that measurements available at the time revealed no statistically significant change in total column ozone, and noted that the WMO conclusion was consistent with then current atmospheric theories and models.

EPA also noted, however, recently released preliminary evidence that suggested some depletion of stratospheric ozone had already occurred. It described the recently discovered seasonal "hole" in the ozone layer above Antarctica and the recent data that strongly suggested anomalous chlorine chemistry plays a role in the hole's formation. EPA concluded, however, that too many questions remained as to the cause and implications of the hole for the Agency to take it into account in its projections of global ozone depletion and, by extension, its regulatory decision-making.

The Agency also noted a recent article containing data that called into question the conclusion that *global* ozone levels had not decreased. Preliminary assessments of the ground-based and satellite measurements suggested that depletion of up to five percent had occurred over the past one or two decades. However, the data suggesting that ozone had depleted globally had not yet been published in the scientific literature and therefore had not yet been thoroughly reviewed. EPA explained that interpretation of such data was complex because of the need to address issues of calibration and instrument drift, among others. In addition to validating and quantifying the trend itself, EPA also cited the need to distinguish ozone losses related to man-made chlorine from those related to natural causes (e.g., solar cycle, volcanic activity). The Agency noted that a thorough review of both that data and research on the Antarctic ozone hole had been recently initiated by a group of the world's leading atmospheric researchers under the auspices of UNEP, WMO, NASA and NOAA (the Ozone Trends Panel), and decided that until the data had been adequately reviewed and analyzed by the scientific community, it should not be used in its risk assessment or regulatory decision-making.

Environmental groups commenting on EPA's proposal strongly disagreed with the Agency's decision not to factor into its risk assessment and regulatory decision-making the Antarctic hole and global ozone trends data. While apparently acknowledging that at the time of the proposal there was inadequate evidence linking CFCs with the Antarctic hole, they argued that a scientific consensus had since emerged that CFCs are a cause of the hole. They also asserted that the Ozone Trend Panel's review of the ozone trends data was "expected" to conclude that ozone depletion of several percent had already occurred. Many industry commenters, on the other hand, agreed with the Agency's judgment that the Antarctic and global ozone trends data were either too preliminary or inconclusive to provide a basis for regulatory action. But some of these commenters complained that the Agency focused too much on the data, given its judgment that the data were insufficient to support regulatory action.

EPA stands by its conclusion that the Agency should not rely on the preliminary evidence of either the Antarctic hole phenomenon or apparent global ozone depletion in this rulemaking. As discussed earlier, Congress gave EPA broad discretion to weigh the available evidence, but it indicated that the Agency should base regulatory decisions on evidence that "is adequately adduced" and "reasonably reliable." Relatedly, Congress did not intend EPA to protect against any risk of ozone depletion; it instead authorized EPA to regulate in the case of risks it finds "will endanger" public health and welfare.

EPA judged that the preliminary Antarctic ozone hole data was insufficient to conclude that public health and welfare would be "endangered" by the hole's existence. The preliminary data left unanswered important questions like whether the mechanisms causing the hole are unique to Antarctica, whether losses in Antarctica alone influence global ozone levels, and whether the hole will have other direct and indirect effects on the rest of the world. At the time of the December proposal, the preliminary global ozone trends data, in turn, were not adequately adduced or reasonably reliable for purposes of assessing risks or making regulatory decisions. The data was not peer-reviewed for accuracy and significance and the Agency could not rely on "expectations" of what that review would show. In the case of ozone measurements, peer review is particularly important because of the difficult issues of interpretation they pose. EPA thus found it appropriate to await completion of the Ozone

Trends Panel review of the data before basing its risk assessment and regulatory decisions upon it.

Industry concerns that EPA overemphasized the preliminary data are also misplaced. As noted above, EPA carefully described the limitations of the data concerning these phenomenon and expressly rejected relying on the data in this rulemaking. Moreover, the atmospheric models used in its risk assessment and RIA do not account either for the Antarctic ozone hole or for observed losses in ozone during the decade.

2. Ozone Trends Panel Report

In March of this year, the Ozone Trends Panel released the executive summary of its report; release of the body of the report is expected in August. The panel concluded that stratospheric ozone has already been depleted on a global basis more than researchers had previously thought, though not as much as the preliminary satellite data had suggested. The panel also stated that "the observed changes [in global ozone] may be due wholely, or in part, to the increased atmospheric abundance of trace gases, primarily [CFCs]," and that the Antarctic ozone hole is clearly linked to CFCs. An obvious implication of its conclusions is that EPA's risk assessment probably underestimates the risk of ozone depletion.

Notwithstanding the likely significance of the Ozone Trends Panel report, EPA is not in a position to consider it in this rulemaking. As noted above, the full report, including the data and analyses supporting the summary's conclusions, are not yet available for either the Agency or the public to review. Before relying on the summary's conclusions, EPA has the responsibility to review the underlying report; the Agency cannot delegate its duty to make an informed judgment on the adequacy and implications of the new information.

Even if EPA could rely on the report's summary alone, the Clean Air Act would require that the public be given an opportunity to comment on the summary if the Agency intended to base its regulatory decision on it. However, the August 1 court-ordered deadline governing this rulemaking did not leave sufficient time for the Agency to provide the public with a meaningful chance to comment on the summary's significance for the proposed rule. The scientific community will require at least several months to perform the analyses and model revisions needed to assess the significance of the new information. Complicated analysis will be required to determine what aspects of current atmospheric models must be altered to more accurately reflect recent changes in ozone levels both in the Antarctic and globally. EPA will then have to review these model changes and undertake its own assessment of risks. This effort would have left too little time to publish and obtain comment on any revised risk assessment and regulatory response and still meet the August deadline for a final rule.

Moreover, even if no court-ordered deadline pertained to this rulemaking, EPA could not have delayed the rulemaking to the extent analyzing and providing public comment on the summary would have required. The Protocol's freeze may take effect as early as July of next year; if EPA is to provide industry with leadtime to comply with the freeze, it cannot long delay promulgation of the final rule.

The Agency is nonetheless concerned about the implications of the conclusions drawn by the Ozone Trends Panel. Administrator Thomas, in an April 7, 1988 letter, has called on the Executive Director of UNEP to expedite the Protocol's review process to allow parties to determine at the earliest possible date the need for additional restrictions. The United States, along with other countries, is now actively engaged in planning for the review on an expedited schedule following entry into force of the Protocol. Under the revised schedule, the assessments called for in the Protocol are tentatively scheduled to be completed by mid-1989, which would allow the Parties to meet to begin considering the need for additional steps by fall of next year.

EPA is also in the process of updating its risk assessment and will evaluate the Ozone Trends Panel report and all other new scientific information in the updated assessment. Assuming the panel's full report is released in August, EPA expects to complete its update by early 1989. EPA discusses further the summary findings of the Ozone Trends Panel in the ANPRM also published today in the **Federal Register**, and states that it intends to seek public comment on the full report when it becomes available. Based on its revised Risk Assessment, the Agency will determine what further actions, if any, are necessary.

3. Use of Atmospheric Models in Predicting Future Ozone Depletion

Direct measurements indicate past changes in ozone levels, but atmospheric models are the only available tool for predicting future trends in ozone. These models, in more or less detail, attempt to replicate the forces that determine ozone levels. Two basic types of atmospheric models have been developed. One-dimensional (1-D) models predict ozone levels on a globally averaged basis, while two-dimensional (2-D) models also predict ozone levels by latitude and season.

For its risk assessment and RIA, EPA used a simplified version of a 1-D model to analyze different scenarios of ozone-modifying gas growth and control. In the preamble to its December 14 proposal, the Agency explained that while 2-D models provide more information relevant to calculating the impacts of depletion, they are expensive and time-consuming to use and far from uniform in their results. The Agency recognized the relative limitations of 1-D models, but concluded that they were the best available tools for the purposes of risk assessment (e.g., analyzing the impact on depletion of many different control scenarios).

Several commenters raised issues concerning EPA's use of a simplified 1-D model as its primary risk assessment tool. One chemical producer urged that the full 1-D model, as opposed to the simplification, be used for regulatory decision-making, and added that the model the Agency used was outdated. Several environmental groups argued that EPA should have used the more sophisticated 2-D models.

The Agency chose to use the parameterized version of the 1-D model because it provided a relatively low-cost means of analyzing different trace gas scenarios without losing much of the original model's precision. Under the auspices of UNEP, results of the parameterized model EPA used were compared with results from the major 1-D models of the world. The study concluded that "[w]ithin the existing limitation of models to accurately simulate the real stratosphere, all models including the fully parameterized model, predicted, within acceptable limits, similar ozone depletions for given control scenarios."

As noted by one of the commenters, the parameterization EPA used was revised following preparation of the original risk assessment. Minor changes in several coefficients were made. However, the revised and original methods gave essentially the same results, so EPA continued to use for its RIA the original version of the model which had been reviewed and approved by the SAB.

The Agency chose not to use 2-D models because, not only are they substantially more expensive and time-consuming to use, but there is much less agreement between 2-D model results than now exists for 1-D models. While all 2-D models show that ozone

depletion varies with latitude, they differ widely in the size of the latitudinal gradient they project and even in what hemisphere they predict a gradient. These differences reflect the fact that 2-D models are attempting to replicate atmospheric transport mechanisms that are extremely complex and not yet well understood. While 2-D models are potentially powerful in their predictive capacities, they still require substantial development. What can be gleaned from them now is the basic finding that ozone depletion will be greater at higher latitudes and may be greater on a global average than 1-D models predict. In comparing these two types of models, the 1987 WMO assessment concluded that, "[t]here is no indication at present that results from two-dimensional models should invalidate in a gross sense assessment studies with one-dimensional models."

A more fundamental fact in considering the choice of models is that no model now exists that accurately mirrors the complex processes which affect stratospheric ozone; the results of all models are approximate, at best. In summarizing the conclusions of its risk assessment, EPA stated, "while the [atmospheric chemistry] models replicate many of the characteristics of the atmosphere accurately, they are inconsistent with measured values of other constituents, thus lowering our confidence in their ability to predict future ozone changes accurately." In short, while models provide the best available tool for evaluating future ozone trends, they provide rough approximations at best. Regardless of the type of model used, the inherent limits of our current ability to precisely predict future atmospheric changes must not be overlooked.

4. Future Trends in Ozone Levels Assuming No Controls

Using the parameterized 1-D model, EPA examined the potential impact of its trace gases scenarios on ozone depletion. Table 2 shows the results of its analysis. For the baseline scenario, depletion is projected to begin around the turn of the century and increase sharply through the next century.

TABLE 2.—Estimated Ozone Depletion for Baseline Scenario

Year	Percent depletion
2000	1.0
2025	4.6
2050	15.7
2075	[1] 50.0

[1] Because of limits in the range of accuracy of the model, ozone depletion was arbitrarily constrained at 50 percent. However, the Agency performed a sensitivity analysis that includes no artificial limit on depletion; it projected depletion in 2075 of 52 percent.

C. Health and Environmental Impacts

Under current atmospheric conditions, the ozone layer blocks most of the damaging ultraviolet radiation (UV-B) from penetrating to the earth's surface. As part of its risk assessment, EPA examined a wide range of potential health and environmental impacts from increased exposure to UV-B radiation as a result of ozone depletion.

Research to date has identified the following areas of potential harm to human health: increased incidence of melanoma and non-melanoma skin cancers and cataracts, and suppression of the immune system. Because the exact nature of the dose-response relationship between increased exposure to UV-B radiation and the incidence of skin cancers and cataracts is uncertain, a range of values were used in the analysis. These estimates are presented in section V, below. Insufficient information exists to quantify potential effects related to immune suppression.

Limited experiments have also linked increased UV-B exposure to damage to plants and aquatic organisms, accelerated weathering of certain manmade materials, and increased formation of ground-level ozone (smog). While studies completed to date suggest that substantial damage in each of these areas is likely, the limited nature of the studies make it difficult to generalize and quantify the potential effects. For its RIA, EPA drew from the existing studies to provide limited estimates of potential damage, but the Agency recognizes that substantially more research in each of these areas is needed. The results of the analysis contained in the RIA are presented below in section V.

Because the gases that affect ozone also contribute to global warming, the Agency's risk assessment also examines the likely health and environmental impact of the greenhouse effect if emissions of these gases continue to grow. Global warming is likely to lead to changes in temperature and precipitation, increased sea level, and changes in storm patterns and frequency. These changes could affect agriculture, forests, development patterns, water quality and a wide range of other health and environmental factors. Given the limited information available to quantify these potential impacts, EPA only included in its RIA a case study of the impact of sea level rise. This is explained in Chapter 8 of the RIA and below in section V.

D. Conclusion

Based on its risk assessment and RIA, the Agency has concluded that continued growth in CFCs and halons will result in substantial ozone-depletion having serious health and environmental consequences. While many uncertainties exist, the current evidence presents a strong case for action to substantially reduce emissions of these most potent ozone depleting chemicals. A comparison of the costs and potential benefits of differing levels of control are discussed below.

IV. Final Rule

A. Scope, Stringency and Timing of Reductions

As noted above, EPA proposed to implement the Montreal Protocol, provided that the Protocol enters into force and the United States ratifies it, which the United States has since done. The Agency explained that United States implementation of the Protocol was an appropriate response to the threat of ozone depletion for two reasons. One, EPA's assessment of available scientific evidence indicated that adherence by the United States along with broad international participation in the Protocol's control requirements would nearly eliminate the projected risk of ozone depletion. Two, EPA judged that the obvious need for broad international adherence to the Protocol counseled against the United States' deviating from the Protocol, because any significant deviation could lessen other countries' motivation to participate. To the extent the Protocol's existing control requirements were later found more or less stringent than necessary to protect stratospheric ozone, EPA noted that key provisions in the agreement afford the Parties the opportunity to review and revise those requirements.

The public comments on the Agency's proposed rule were virtually unanimous in supporting implementation of the Montreal Protocol. Industry and public interest groups alike recognized the need for a global response to this global problem, and embraced the Protocol as a landmark international agreement to address an environmental threat to a critical and irreplaceable resource. These groups and others differed, however, on whether the Protocol's control measures were sufficient to fully protect stratospheric ozone.

In general, CFC producers and users contended that the scientific evidence

on which EPA rested its proposal did not justify the CFC reductions required by the Protocol except as a precautionary measure. They disagreed with EPA's assumptions concerning the future growth rates of several gases affecting ozone (as discussed above) and the likely degree of international compliance with the Protocol, and contended that more realistic assumptions would yield projections of total column ozone remaining stable or actually increasing. They suggested that since the science on which EPA purported to rest its proposal did not justify the required reductions, the Agency must have taken the Antarctic and ozone trends data into account in deciding to seek those reductions.

Industry commenters also generally agreed with EPA's concern that deviating from the Protocol risked undermining it. They recognized that implementation of less stringent controls than the Protocol required would be unacceptable, and shared EPA's concern that implementation of more stringent controls would yield little, if any, additional stratospheric protection, while possibly reducing other countries' incentive to join the Protocol. They added that unilateral action to reduce further ozone-depleting emissions would put United States' industry at a competitive disadvantage in world markets.

In contrast, environmental and other public interest groups claimed that the Montreal Protocol and thus EPA's proposed rule did not go far enough fast enough in requiring reductions in ozone-depleting substances. Several noted EPA's own projections that (1) stratospheric ozone would still be depleted by nearly two percent by the year 2075 under the Protocol's control regime; (2) every one percent decrease in ozone would result in a one to two percent increase in melanoma skin cancer incidence, among other adverse effects; and (3) United States unilateral action to reduce CFC use by an additional 30 percent would further reduce those adverse effects. In light of these projections, they questioned the logic of EPA's proposal to implement the Montreal Protocol's required reductions and no more.

Their chief complaint, however, was that EPA failed to propose the virtual phaseout of CFCs and halons that they claim is needed based on the preliminary Antarctic ozone hole and global ozone trends data. In its comments on the May 24 NPRM proposing company-specific allocations of production and consumption rights, one environmental group noted that the Ozone Trends Panel summary concluded in March that ozone-depletion had already occurred and that CFCs and halons appeared at least partly responsible. The commenter also pointed to data released in May supporting the existence of a smaller Arctic version of the Antarctic ozone hole, and argued that both developments made clear that a phaseout was required to protect stratospheric ozone.

Several commenters also faulted the Agency for essentially relying on continued uncontrolled growth of other greenhouse gases to buffer the ozone-depleting effects of CFCs and halons. They disagreed, moreover, with EPA's judgment that unilateral United States reductions beyond those required by the Protocol ran a significant risk of undermining the efficacy of that agreement. They argued that EPA could and should use its authority under section 157(b) of the Act to leverage further reductions from other countries by immediately imposing restrictions on the import of products containing or made with CFCs from countries that fail to agree to make the same reductions.

Finally, a number of commenters disagreed with EPA's proposal to make the regulations effective upon the Protocol's entry into force. Again, they stated that the severity of the ozone depletion problem warrants faster action than the Protocol requires and that unilateral United States action would not seriously undermine the incentive of other countries to join the Protocol.

B. Basis for Control Requirements

After carefully considering the comments received, EPA has concluded that implementation of the Montreal Protocol is the best course the Agency can take at this time to securing adequate protection of stratospheric ozone.

EPA's decision to implement the Protocol has two bases. One, EPA believes that the scientific information and analyses available to the Agency and public in this rulemaking support a finding that the Protocol's control requirements are needed and reasonably adequate to protect stratospheric ozone. For the reasons discussed earlier, EPA considers the preliminary nature of the data on the Antarctic ozone hole and global ozone trends provides an insufficient basis for regulatory action. The Agency recognizes that the summary of the Ozone Trends Panel Report released several months ago assessed that data and raised questions about the adequacy of the Protocol's controls. However, as explained above, adequate evaluation of that report and other recently available information could not be completed before the close of this rulemaking. EPA also believes for reasons mentioned earlier that it reasonably considered the need to control ozone-depleting substances independently of the need to control other greenhouse gases.

Two, EPA believes that the Montreal Protocol's international response represents the most effective means of protecting the ozone layer. Unilateral action by the United States would not significantly add to efforts to protect the ozone layer and could even be counterproductive by undermining other nations' incentive to participate in the Protocol. The Agency believes that the best way to deal with the challenges posed by new information is through the Protocol's review and revision process, and at the Administrator's request, UNEP has agreed to expedite that process so that the Parties may consider at the earliest possible date whether additional international reductions are warranted. EPA's analysis indicates that if further reductions are required, they may be undertaken after the expedited review process is completed and still be effective in achieving stratospheric protection.

1. Scope of Coverage

The final rule governs future production and consumption of CFC–11, –12, –113, –115 and Halon 1211, 1301 and 2402. These chemicals are covered by the Protocol and, as explained in the preamble to the proposed rule, currently pose the greatest threat to stratospheric ozone.

The Agency received one comment that took issue with the scope of chemicals proposed for regulation. The commenter, a halon producer, pointed out that EPA's projections show that freezing the growth of halons will not reduce ozone losses until well into the next century, and that a case could thus be made for not regulating halons at this time. The Agency points out, however, that halons' long atmospheric lifetimes require that action to control their use be taken now to prevent the ozone depletion EPA projects for the future. Halon 1301, for instance, has an estimated lifetime of 110 years; thus, emissions of this chemical today will contribute to ozone depletion far into the next century. In addition, if left unregulated, halons could grow in use. To prevent halons from becoming a greater threat to the ozone layer, EPA must limit their supply in the near term.

2. Stringency and Timing of Controls

The final rule also adopts the stringency and timing of the Protocol's control measures. Taken together with the scope of chemicals covered by the rule, EPA believes based on the information in the record that its rule is an appropriate response to the risk of stratospheric ozone depletion.

Table 3 shows model projections of ozone depletion for different levels of reductions. As explained earlier, EPA has revised its ozone depletion projections to reflect higher CFC growth for 1987 and slightly higher CFC growth rates through 1992. The revised projections indicate that broad international implementation of the Protocol's control measures (case 3) is likely to reduce future ozone depletion from over 50 percent to less than 2 percent in the year 2075, with further reductions in depletion occurring after that date as ozone increases from additional methane and carbon dioxide more than offset losses from CFCs and halons (see chapter 6 of the RIA). The projections also illustrate that unilateral implementation of the Protocol's control measures by the United States, with no other nations reducing their use of CFCs and halons (case 4), would halve projected depletion by 2075, but that substantial depletion would still occur.

Even assuming that the United States unilaterally decreased CFC use by 85 percent by 1998 (case 5), this action would only reduce projections of ozone depletion by 0.3 percent in 2075 compared to the Protocol case (case 3). If the United States unilaterally accelerated its reductions and decreased by 85 percent by 1992 (case 6), projections of ozone depletion in 2075 would only be reduced by another 0.2 percent. These cases also assume that United States unilateral action beyond the Protocol would not reduce participation by the other nations in that agreement. In contrast, should the international community decide in the future that reductions beyond the Protocol are proper, a multilateral reduction of 85 percent by 1998 would result in substantially greater protection than that achieved by unilateral action (case 7).

TABLE 3.—SUMMARY OF OZONE DEPLETION ESTIMATED FOR THE 8 CONTROL CASES [a]

[Ozone depletion reported in percent]

Case	2000	2025	2050	2075
1. No Controls (baseline) [b]	1.0	4.6	15.7	50.0

TABLE 3.—SUMMARY OF OZONE DEPLETION ESTIMATED FOR THE 8 CONTROL CASES [a]—Continued

[Ozone depletion reported in percent]

Case	2000	2025	2050	2075
2. CFC Freeze Only—International	.8	2.5	4.7	6.9
3. CFC 50%/Halon Freeze—International (Protocol Case)	.8	1.5	1.9	1.9
4. CFC 50%/Halon Freeze—United States only	.9	3.5	10.3	27.4
5. CFC 50%/Halon Freeze—International; CFCs—85% (1998)—U.S. only	.8	1.3	1.7	1.6
6. CFC 50%/Halon Freeze—International; CFCs 85% (1992)— U.S. only	.8	1.2	1.5	1.4
7. CFC 85%/Halon Freeze—International (1998)	.8	.9	.8	.3

[a] Cases 2, 3, 5, 6 and 7 assume 94 percent participation for other developed countries, and 65 percent participation for developing countries, based on countries participating in Protocol negotiations.
[b] Global ozone depletion is arbitrarily constrained at 50 percent in this analysis.

EPA disagrees with some industry comments that the Agency's own projections in the risk assessment show that a *freeze* in controlled substances would result in an *increase* in total column ozone and thus that current scientific information does not justify the Protocol's reduction requirements. EPA notes that this particular scenario in the risk assessment assumed a total freeze in HCFC 22, methyl chloroform and carbon tetrachloride, as well as the chemicals covered by the Protocol, along with all nations in the world participating; the projections made here and in the accompanying RIA showing that the Protocol's controls would still result in a small degree of ozone depletion do *not* assume a freeze in chemicals outside the coverage of the Protocol. This difference in assumptions accounts for the difference in projections.

EPA also disagrees with comments suggesting that additional reductions beyond the Protocol are necessary for the Agency to meet its obligations under the Clean Air Act. As Table 3 illustrates, based on the information which could be considered in the course of this rulemaking, EPA's analysis shows that the model's projected ozone depletion would be reduced to a level of less than two percent. EPA believes that, given the scientific and technical limitations of its analysis and the need to obtain international agreement to achieve effective controls, additional unilateral reductions are not warranted at this time.

a. Limitations in Atmospheric Models. While atmospheric chemistry models are the best available tools for estimating future changes in ozone depletion, they are far from exact. As discussed above and in both the WMO and EPA assessments, these models accurately reproduce some aspects of the current atmosphere but fall far short of replicating other aspects. As a result of these acknowledged deficiencies, rigidly tying the stringency of controls to the projections of these models is not warranted or appropriate. Moreover, Table 3 illustrates that based on current models, little difference in depletion occurs until the turn of the century. During this period additional measures could be taken through the Protocol process if needed. For example, more stringent reductions on CFCs or the addition of such chemicals as methyl chloroform (which has a shorter atmospheric lifetime) to the Protocol could achieve further reductions in potential ozone depletion.

b. Limitations in Long-Term Projections. Results from the atmospheric models are further limited by uncertainties concerning growth in trace gases which affect ozone. While EPA believes that its trace gas growth assumptions accurately reflect current understanding of likely future trends, the Agency recognizes the inherent limits in making projections that cover more than a century. Some of these projections (e.g., CFC growth rates) are based on factors such as long term economic growth and technological development which cannot be predicted with precision. Others (e.g., methane, carbon dioxide and nitrous oxide growth) are based on recent history, which may not prove an accurate indicator of future trends. Still others are based on behavioral assumptions (e.g. participation in the Protocol) which cannot be readily tested.

Given these limits, the reduction in ozone depletion that a specified control limit will provide cannot be foretold with precision. Recognizing this, the Protocol negotiators agreed to a 50 percent reduction in CFCs in part because a reduction of this magnitude would provide an incentive for development of chemical substitutes which in turn would facilitate even greater reductions if such proved necessary. The analysis in the RIA assumes that CFC use is reduced by 50 percent in 1998 as called for in the Protocol. Yet several large producers and users of ozone-depleting substances have recently announced their

intentions to phase down below this level or even phase out of these chemicals. If this occurs, the RIA's analysis could actually overstate the amount of long-term ozone depletion which could result.

As part of its sensitivity analysis contained in the RIA, the Agency considered many of the issues raised by commenters. The analysis examined alternative assumptions in the following areas: higher and lower growth in methane, carbon dioxide and nitrous oxide; different rates of participation by developed and developing nations in the Montreal Protocol; and different baseline growth rates of CFCs. The results of this sensitivity analysis illustrate that projected ozone depletion could increase or decrease (or that ozone could even slightly accrete) under certain scenarios for any of a number of reasons. Given that recognized uncertainties in the analysis are on the same order of magnitude as the projected residual depletion, EPA believes that it would not be reasonable necessarily to require controls to eliminate the residual depletion. Other factors, such as the opportunity to revise the Protocol as new information warrants and the need for broad Protocol participation, are also important in deciding how much control to require now.

c. International Considerations. As shown in Table 3, concerted international action represents the only effective means to safeguard the ozone layer. EPA firmly believes that the ratification and implementation of the Montreal Protocol provides the most effective means of achieving that objective. As explained below, the history leading to the Protocol provides ample evidence that unilateral action by the United States would not necessarily ensure adequate protection for the ozone layer.

In 1978 the United States restricted the use of CFCs in aerosols. While several nations adopted similar restrictions (e.g., Sweden, Canada, Norway) and others partially cut back this use (European nations, Japan), there was no widespread movement to follow the United States' lead. Concerns existed then that other nations had failed to act because the United States and a few other nations were making the reductions thought necessary to protect the ozone layer. Similar concerns exist today that unilateral action could result in "free riding" by some other nations.

More recently, negotiations leading to the Montreal Protocol can be traced back to the early 1980s. The initial round of negotiations were concluded in 1985 when the involved nations agreed on the Vienna Convention for the Protection of the Ozone Layer but failed to agree on specific actions to limit ozone-depleting chemicals. This failure resulted, in part, from the fact that some nations had already taken different interim approaches to limiting CFCs and from the lack of a common understanding of the underlying science and risks. During the year following the first round of negotiations and leading up to the second, a major international assessment of atmospheric issues was conducted (WMO assessment) and international workshops on health and environmental effects and on economic and technological issues were convened. These assessments provided the common base of information which led in September 1987 to agreement on the Montreal Protocol.

Thus, in past efforts to obtain international controls, the United States has been most effective not by taking unilateral action but instead by actively participating in international assessments and by aggressively pursuing a strong global agreement.

Recognizing the utility of the international assessment process and the significant scientific, technical, economic and environmental uncertainties that remain, the Protocol explicitly provides for periodic "assessment and review of control measures." EPA believes that this process, as agreed to by nations becoming Party to the Protocol, represents the most effective vehicle for obtaining further reductions, if such prove necessary. But the essential first step is satisfying the conditions for entry into force. EPA's Administrator sent a letter to his counterparts in May of this year urging their ratification of the Protocol. Based on recent information, it appears that the January 1, 1989 target date for entry into force will be met.

Once entry into force has occurred, the next step will be to conduct the assessments called for in the Protocol on an expedited schedule and allow the Parties to decide if additional actions are warranted. As discussed above, EPA has initiated several actions to facilitate that process, and UNEP's schedule for assessment and review has been moved forward in time.

Given that the Protocol process appears likely to be effective in addressing the need for additional controls in a timely manner, EPA believes that unilateral action by the United States would not significantly contribute to protecting the ozone layer and might even make it more difficult to utilize the Protocol process to achieve the necessary international consensus for action. Unilateral United States action could appear to reduce the urgency of reviewing the Protocol's control measures, and unilateral actions accompanied by trade sanctions, such as some commenters suggest, could lead to counteractions well beyond the scope of protecting stratospheric ozone, making future agreement more difficult.

EPA also rejects several commenters' suggestion that EPA's regulation should take effect immediately and not be linked to entry into force of the Protocol. EPA believes that the environmental benefits from delaying implementation for a few months would be small compared to potentially large economic costs to United States industry of acting in advance of other Parties to the Protocol. Entry into force now appears likely by January 1, 1989. With success so near, EPA does not want to take unilateral action that could reduce the impetus for other nations to join the Protocol in a timely manner.

C. Selection of Regulatory System

EPA considered many different strategies for implementing the requirements of the Montreal Protocol including traditional engineering controls and economic based programs. The Agency explained that the latter type of program would utilize free market incentives to achieve cost-effective controls, and suggested three specific options: Auctions, allocated quotas, and regulatory fees. The advantages and disadvantages of each of these options (and possible combinations) were discussed in the December 14 NPRM. While EPA stated that an allocated quota program was its preferred option, it sought and received comment on each of the options. EPA received more comments on its selection of a regulatory strategy than on any other aspect of its December 14 NPRM.

1. Allocated Quota Option

Under this system, producers and importers of CFCs and halons in 1986 would receive production and consumption "rights" or allowances.[1]

[1] In the December 14 NPRM, EPA used the term "rights" to refer to what it proposed to grant producers and importers of CFCs and halons to authorize future production and consumption of these chemicals. The Agency noted, however, that "rights" was used as a matter of convenience, and that what EPA proposed to grant was actually in the nature of a privilege. One commenter suggested that EPA avoid the use of such a shorthand term and therefore the need to explain it. EPA agrees and has in the final rule and this preamble used the term "allowances" instead.

The majority of commenters addressing this point, including chemical manufacturers and most major CFC and halon user groups, supported EPA's preference for the allocated quota system for many of the same reasons discussed in the December NPRM: It would ensure that the control requirements of the Protocol are achieved; would provide for low cost, market-based reductions; and would be administratively straightforward.

While generally supporting the allocated quota approach, a large number of respondents from the foam-blowing industry argued that they would be inadvertently discriminated against under such a system because chemical producers would shift production away from CFC-11 (the primary chemical they use) to other, more profitable CFCs. They also claimed that since CFCs are a large percentage of their final product costs, but only a small percentage of the product costs of other CFC-using industries (e.g., computers, refrigerators, and car air conditioners), future CFC price increases will have a greater effect on their industry. As a result of these concerns, they argued that EPA should provide a set-aside for their industry based on their 1986 use.

EPA considered this request, but at this time believes that the disadvantages of creating such a set-aside substantially outweigh any possible advantages. EPA has no information about whether chemical producers will shift production away from CFC-11 to other CFCs. Several producers have publicly stated that, consistent with anti-trust requirements, they intend to utilize their quotas to minimize disruption in user markets by allocating allowable supplies to past customers. While EPA doubts that producers will make allocations that reduce their ability to earn profits, to the extent producers allocate CFC-11 to foam blowers, their concerns will be obviated. In the longer term, which chemicals will be produced is difficult to discern. It will depend largely on the relative timing of chemical substitutes. For example, to the extent chemical substitutes for CFC-12 and CFC-113 become available before substitutes for CFC-11, within the limits established by the Protocol, even more CFC-11 than is produced today could be produced in the future.

Providing a set-aside for one industry segment would also be economically inefficient. If EPA adopted the system proposed by the foam-blowers, the Agency would be subsidizing that industry at the expense of all other CFC users. Other industries would have access to a reduced supply of CFCs (the allowable level minus the set-aside) and would therefore pay higher market prices. Since foam-blowers would not have to compete against firms from other user industries, they would likely pay lower CFC prices and consequently have less incentive to reduce their use of these chemicals. Moreover, many segments of the foam-blowing industry (e.g., foam packaging and flexible molded foam) have inexpensive alternatives available today and therefore would not need a set-aside.

Finally, the foam-blowers' concerns relate primarily to their alleged inability to pay higher prices for CFCs. The magnitude of future price increases will depend on the speed and rate of reductions taken by all industries particulary in the next few years. (See Section V, below.) As discussed at length in the accompanying ANPRM, EPA intends to closely monitor progress in achieving reductions across all CFC user industries, and may propose to require reductions where they are available but are not being aggressively pursued by a particular user industry. According to the RIA (Chapter 9 and Appendix M), if such reductions are achieved in a timely manner, price increases would be substantially moderated and the concerns raised by the foam-blowing industry would never materialize. This analysis is presented in detail in Section V, below which describes the analysis contained in the RIA accompanying this rule.

Several auto companies, two government agencies, and several environmental groups were concerned that an allocated quota system would provide substantial market power and sizable windfalls to a small number of producers. These commenters feared that producers would have an economic incentive to delay the introduction of chemical substitutes which would thus raise the cost of reducing use of ozone depleting chemicals. They also feared that producers might restrict supply beyond the limits in the regulation, further increasing CFC prices. In addition, one of the commenters was concerned that allocated quotas alone would, in effect, create a system under which polluters would profit from their pollution.

EPA shares these commenter's concerns that windfall profits could induce producers to delay the introduction of chemical substitutes. It also recognizes the irony that regulation by means of an allocated quota system could make money for the regulated industry. Despite these drawbacks, however, EPA is confident that an allocated quota system would still bring about the required reductions in controlled substances, although at a higher cost if substitutes are delayed. Since the quotas would directly limit production and import of controlled substances, they would ensure that the Protocol's limits are met. But should producers delay the introduction of substitutes, the cost to society of meeting those limits would be higher than it would otherwise be; prices of controlled substances and prices of products using controlled substances would be driven higher or remain high for a longer period of time.

Six chemical producers and an industry trade association argued that EPA had incorrectly characterized the nature and magnitude of profits that would result from allocated quotas (e.g., by not taking into account higher production costs and taxes) and that higher prices for controlled substances are necessary to fund the development of new chemical substitutes. EPA believes that it has correctly portrayed the nature of the likely windfalls (i.e., transfers) which would result from the allocated system. EPA agrees that the costs of production of each unit of controlled substances might increase as the quantity of production is cut and that increased prices for controlled substances will also result in increased taxes paid to the U.S. Treasury. But these points do not materially alter the analysis of windfalls presented in the RIA. The unit costs of feedstock materials, which constitute the majority of production costs, are not likely to significantly increase. While the payment of taxes may decrease the actual profits to producers, the amount of this payment to the Treasury will depend on many factors (e.g., corporate income tax rates) outside the scope of this analysis. Moreover, losses due to the shutdown of existing production facilities are also uncertain. Instead of being closed, existing production facilities may be modified, in some cases to produce chemical substitutes (e.g., HCFC-22) or used to produce feedstocks for new chemicals. The ANPRM also published today in the **Federal Register** contains a more detailed discussion of the issue of windfalls and their long-term environmental and economic implications.

2. Regulatory Fees

Regulatory fees were also offered as an option in the December 14 NPRM. In that notice, EPA raised the issue that fees, by themselves, would not ensure that the required control levels were met and therefore that the United States'

obligation under the Montreal Protocol were fulfilled. EPA would not be able to accurately predict how many firms would elect to pay the fee and continue using CFCs and halons and how many would instead elect to reduce their consumption of these chemicals. EPA also questioned and requested comment on its legal authority under the Clean Air Act and Toxic Substances Control Act to impose a regulatory fee.

Many commenters agreed that a fee alone would not be an effective regulatory program since EPA would not be able to set the fee at the correct amount to achieve the required levels of control. Ten commenters supported the use of a fee to reduce the windfall to producers and thus, the incentive the windfall might have created to delay the introduction of substitutes. But others, primarily from the foam-blowing industry, objected to the use of a fee on the grounds that it would unnecessarily increase their costs of doing business.

Implicit in their argument is an assumption that any fee would be added to the price of CFCs and halons above and beyond increases created by market scarcity. Economic theory as described in two analyses sponsored by EPA, however, suggests that fees would not increase the price of controlled substances in such a manner. (Decanio, 1988 and Sobotka, 1988.) As long as the fee is set below the increase in price resulting from the limit on supply of CFCs, user industries would pay the same amount under either a fee system or an allocated quota system. Price increases would be limited by the forces of supply and demand regardless of whether they result from a fee or regulatory mandated scarcity. With fees, however, the windfalls go to the United States Treasury, while under a quota system, the transfers would go to the producers.

Under a system combining fees and allocated quotas, the cost to users would also be the same as either of these systems alone, and the transfers would accrue to the United States Treasury. As a result, adding a regulatory fee to an allocated quota system would not raise the price of CFCs and halons to users but would remove any potential advantage for a producer to delay or reduce the supply of chemical substitutes.

Commenters disagreed about whether EPA has legal authority to impose regulatory fees. Several public interest groups contended that section 157(b) of the Clean Air Act is sufficiently broad to permit EPA to use fees as a regulatory method. On the other hand, some chemical producers and a trade association asserted that EPA could levy fees, if at all, only to recoup the administrative cost of the program; fees sufficiently high to raise prices of controlled substances enough to reduce demand were beyond EPA's authority. These commenters also argued that to comply with the Clean Air Act's notice-and-comment rulemaking requirements, EPA would have to propose a more specific regulatory fee program before it could promulgate such a program. The Agency believes that the issues surrounding institution of a fees program deserve further attention, and in any event agrees that the December 14 NPRM did not provide adequate notice of what fee EPA would impose. The Agency has therefore decided to conduct further rulemaking on fees, as explained in the ANPR also published today.

3. Auctioned Rights

Instead of granting production and consumption allowances to past producers and importers, EPA sought comment on the use of an auction as the means of distributing allowances. Under this system, production and consumption allowances would be sold at auction to the highest bidder. Anyone seeking to produce or import CFCs or halons could purchase allowances directly at auction. To the extent chemical producers or distributors obtained allowances at auction, user industries could rely on their existing channels of supply to provide these chemicals. Alternatively, user firms could also obtain allowances directly through an auction or purchase them through a secondary market.

The December 14 NPRM discussed several key advantages (e.g., economic efficiency, transfers to the U.S. Treasury) and potential disadvantages (e.g., short-term speculation and hoarding) of this approach.

Chemical producers and a wide spectrum of CFC and halon user industries voiced opposition to an auction system. These commenters raised many of the concerns identified in the NPRM. They suggested that auctions would lead to speculation and hoarding, thus unnecessarily driving up the price of CFCs and halons. Others commented that regulation by auction fell outside EPA's legal authority. They also stated that this approach would be unfair to small businesses who would be unable to compete in an auction and would make planning difficult for producers.

In contrast, two automobile companies and three government agencies supported the use of auctions as an efficient and equitable regulatory system. Further, one government agency argued that speculation would increase rather than decrease market stability. One agency and several public interest groups also contended that EPA has the legal authority to use an auction to achieve its regulatory goal.

EPA believes that many of the concerns raised by industry would be short term. As a market price developed for CFCs and halons over time, any problems associated with hoarding and speculation would likely be diminished. However, because the next several years are critical in the transition to reduced reliance on CFCs and halons, EPA is concerned that these problems, if they did occur in the short-term, could significantly hamper a smooth transition away from ozone-depleting substances. EPA also recognizes that, like fees, auctions are a novel regulatory approach and consequently raise issues about the Agency's authority to employ them. EPA is concerned that a successful challenge to this regulatory approach would disrupt United States' compliance with the Montreal Protocol.

In the ANRM also published in today's **Federal Register**, EPA seeks additional public comment on the desirability of shifting to an auction system and a possible design feature to address the concerns raised by commenters.

4. Engineering Controls and Product Bans

EPA also requested public comment on the use of industry-specific engineering controls—the Agency's traditional approach to pollution control—to implement the Protocol. Thirty-two commenters stated that they opposed the use of EPA-mandated engineering controls or bans. These commenters provided many reasons against the use of this approach including: Reduced economic efficiency; increased administrative costs; inequitable treatment of industries (some would be regulated while others would not); failure to provide an across-the-board incentive for the development of chemical substitutes; and lack of assurance that the control requirement's goal would be achieved (e.g., increases in unregulated uses could offset required reductions).

In contrast, several environmental groups and many foam blowers-supported the adoption of EPA-mandated engineering controls for industries with low-cost control options. These commenters argued that requiring such reductions would ensure that low-cost measures would be taken in a timely manner which, in turn, would minimize CFC and halon price increases

for all users. Several foam-blowers specifically supported engineering controls as a means of ensuring that other industries undertake cost-effective reductions available to them instead of deciding to continue to use CFCs and pay the higher prices. Other members of the foam industry suggested that EPA establish a "trigger event" (such as an increase in CFC price beyond an established guideline) after which the Agency would mandate controls.

In short, economic incentives as employed in an allocated quota system may not be enough to ensure the most cost-efficient control of CFCs and halons possible. At the same time, EPA is still mindful of the drawbacks of using industry-specific engineering controls and product bans. It also acknowledges that the December 14 NPRM did not propose any particular control or ban with enough specificity to permit the Agency to promulgate it in this rulemaking.

EPA intends to continually monitor progress made by each user industry to reduce its use of CFCs and halons. If the Agency determines that cost-effective controls exist but are not being adopted in a timely manner, it may require such actions. The ANPRM accompanying this final action discusses the specific circumstances which could lead to EPA-mandated control requirements.

5. Other Systems

Comments were also submitted on other regulatory options which were briefly mentioned in the December 14 NPRM. For example, several representatives of the auto industry supported a user (instead of producer) allocation system. Under this system, EPA would allocate allowances to the approximately 5,000–10,000 customers who purchase CFCs directly from chemical producers. The commenters did not suggest how this mammoth allocation might be accomplished, only that EPA could assess an administrative fee to pay for the costs.

EPA does not believe that a user allocation system would be feasible. Perhaps the simplest approach to making user allocations would be for EPA to obtain 1986 sales list from CFC producers and publish them for comment as the basis for its allocation. However, based on its recent experience in developing allocations for less than 30 producers and importers, the time and resources required to process and verify claims would be much more than the Agency has available and could not be completed before the Protocol's likely effective date (January 1, 1989). Also, user allocations based on sales records would require release of information that would be claimed confidential.

EPA considered allocating production rights to producers and auctioning consumption rights to users. However, because producers would still maintain control over production in this system, their market power would not be substantially diminished. Users could seek to buy controlled substances that are imports instead of domestic production, but since foreign producers must also live within the Protocol's limits (or have their imports banned by the Parties), the availability of imports of controlled substances would be restricted, leaving the market power of the domestic producers largely intact. In any event, EPA does not want to create a system that encourages greater reliance on CFC and halon imports.

6. Selection of the Allocated Quota System

EPA has concluded that the allocated quota system is the appropriate method for implementing the Montreal Protocol for several reasons. One, by directly regulating the supply of CFCs and halons, the allocated quota system is a straightforward method of ensuring that the requirements of the Montreal Protocol are met. Two, it is clearly lawful, in contrast to the auction and regulatory fee systems which raise legal issues. Three, as a market-based approach, the allocated quota system is economically efficient. Four, it is relatively simple to administer, since the producers and importers subject to the allocated quotas are small in number. While EPA recognizes that an allocated quota system has the potential for windfall profits and the concentration of market power in relatively few companies, it does not believe those disadvantages would prevent the system from bringing about the reductions in ozone-depleting substances required by the Protocol.

The Agency did not select regulatory fees as its implementing strategy because fees alone would not ensure compliance with the Montreal Protocol. It is quite possible that more firms would decide to pay the fee and continue using the CFCs and halons than should if the United States is to comply with the Protocol. Moreover, EPA's authority to administer a regulatory fee program is uncertain.

Like fees, engineering controls or bans could not ensure compliance with the Protocol, since uses of CFCs and halons that are left unregulated could continue to grow, thereby offsetting reductions in the regulated uses. Engineering controls or bans are also difficult to administer considering that thousands of firms use CFCs and halons.

The auction approach, like other market-based programs, is economically efficient. However, commenters expressed concern that auctions, at least initially, would create large uncertainties about price and availability and could lead to speculation and short term hoarding of permits during the auction process. Further, legal questions exist about EPA's statutory authority to implement an auction system. However, because auctions are a market-based system which, if, adopted, would ensure compliance with the Montreal Protocol and shift some of the windfalls from the producers to the United States Treasury, EPA is seeking additional public comment in the ANPR on the desirability of shifting to this approach.

EPA has selected the allocated quota system rather than other strategies, given the allocated quota system's capability of implementing the Montreal Protocol in an economically efficient, low cost manner and the legal and other concerns associated with other systems. However, EPA recognizes that the use of an allocated quota system standing alone could result in substantial windfalls to a small number of CFC and halon producers which could create an economic incentive for these firms to delay the introduction of chemical substitutes.

Because of this concern, EPA is continuing to examine several alternatives to the use of an allocated quota system alone. In the advance notice of proposed rulemaking (ANPRM) which is also published in today's **Federal Register**. EPA describes and seeks comment on supplementing allocated quotas with a regulatory fee to reduce windfall profits and/or with engineering controls or bans on specific uses of CFCs and halons to ensure that low cost reductions are made in a timely manner. The ANPRM also describes and seeks comment on placing a time limit on the use of allocated quotas and shifting to an allocation system based on auctions.

D. Design of Allocated Quota System

In response to comments on both its December 14 and May 24 NPRMs, EPA has revised several aspects of its allocated quotas system. The following paragraphs explain the operative sections of the rule and highlight any changes from the proposed rule and the rationale for such changes.

1. Effective Date (§ 82.2)

The December 14 NPRM stated that the rule would take effect when the Montreal Protocol entered into force. As noted above, the Protocol will enter into force on January 1, 1989, provided that at least 11 instruments of ratification, acceptance, approval of the Protocol or accession thereto have been deposited by Nations or regional economic integration organizations representing at least two-thirds of estimated global consumption of the controlled substances. If this condition has not been fulfilled by January 1, 1989, the Protocol will enter into force on the 90th day following the date on which the conditions have been fulfilled. (The Protocol also requires that the Vienna Convention first enter into force; the conditions for that agreement to take effect have recently been fulfilled, so that it will enter into force before January 1, 1989.)

Several commenters stated that the rule should not in any way be contingent on the Protocol. Moreover, because firms might increase production and stockpile controlled substances prior to January 1, 1989, the regulations should go into effect immediately upon promulgation.

EPA does not believe that firms will stockpile significant quantities of controlled substances before the rule goes into effect because storage facilities are limited and profit margins in the near term are not likely to make expanding storage economically attractive at this time. In any event, EPA believes that by holding off domestic implementation of the Protocol until it enters into force, the United States will be in a better position to encourage other key nations to ratify the agreement.

There is no question that broad international observance of the Protocol's control requirements is necessary to safeguard the ozone layer. Any reductions the United States could accomplish on its own by implementing the Protocol's requirements before the Protocol enters into force would be small compared to the protection offered by a ratified Protocol. (Although the United States now accounts for about 30 percent of global consumption of controlled substances, if only this nation and a few others limit future consumption, other nations would remain free to *increase* their consumption, making the United States contribution to control increasingly less significant). At the same time, United States' implementation might suggest to more reluctant nations that they need not undertake the required controls right away. EPA thus considers it prudent to stay domestic implementation of the Protocol until it enters into force.

EPA remains optimistic that the conditions for entry into force will be satisfied by the January 1, 1989 target date. Governments throughout Europe, and in Australia, Japan and the Soviet Union are well along in their own process of ratification. Recently, the Administrator of EPA sent a letter to his counterparts in other nations urging their speedy ratification of the Convention and Protocol. EPA intends to continue to closely monitor progress toward ratification. If the Agency at some future date determines that a delay is likely, it will reassess what, if any, action should be taken.

In a change from the December proposal, EPA has made paragraph § 82.13(f)(1) of its rule effective as of September 12, 1988. This requirement relates to the method by which EPA will measure production of CFCs and halons, and requires producers to inform the Agency of their current measurement techniques. EPA needs this information even before the Protocol's target effective date in order to have enough time to prepare compliance monitoring guidelines before the likely date of the first control period, July 1, 1989. If EPA did not obtain this information until after the Protocol entered into force, it could not ensure compliance with the freeze requirement.

2. Definitions (§ 82.3)

EPA received comments on many of its definitions both from respondents to its data collection rule (§ 82.20) and from commenters on its December 14 NPRM. The Agency sought to clarify several of its definitions (e.g., controlled substance, production, importer and exporter) in its May 24 supplementary proposal. This section discusses the key definitions and summarizes comments received on the two NPRMs and the resulting changes in the final rule.

a. Control Periods. In its December 14 NPRM, EPA defined control periods as those periods during which the prohibitions under § 82.4 (limits on production and imports) would apply. It reserved the actual dates of the control periods for future determination, because the timing of the first control period depends on the date of the Protocol's entry into force. EPA must therefore wait until that date is known before it can publish in the **Federal Register** the exact dates for every control period.

EPA sought comment on a further complication in determining control periods. The Protocol specifies 12-month control periods for all three steps in the Group I (i.e., CFCs) reduction schedule (i.e., freeze, 20 and 50 percent reductions). While the Protocol provides that the second step will begin on July 1, 1993, it makes timing of the first step contingent on when the Protocol enters into force. If the Protocol enters into force on January 1, 1989, then the freeze will go into effect on July 1, 1989, and each control period thereafter would last for 12 months without any overlap between step 1 (freeze) and step 2 (20 percent reduction). However, if the Protocol enters into force on any date other than January 1, 1989, then there would be overlapping control periods unless the last control period of the freeze is shortened to less than 12-months.

In its December 14 NPRM, EPA stated that it intended to handle this potential overlap, if it arose, by shortening the last control period in the freeze stage so that no overlap occurred and prorating annual allocations for that truncated control period.

EPA received one comment on this issue from a chemical producer which stated that any control period less than a year could prove disruptive because of the seasonal demand for CFCs. The commenter explained that CFC production increases dramatically during summer months because of higher demand for CFC-12 and-11 as a coolant. A shortened control period with a prorated allocation would prove economically disruptive if it coincided with this period of peak demand. It suggested that EPA should define overlapping control periods with the last freeze control period running into the first control period of the 20 percent reduction stage.

EPA proposed to define the control periods so that no overlap would occur in part because it believed that the drafters of the Protocol did not intend control periods to overlaps. Evidence of this intent is the fact that no overlap will occur if the Protocol enters into force on the target date and that the latter two control periods are defined as consecutive. However, EPA recognizes that the Protocol does define all control periods as lasting 12 months, and that a control period of less than a year could disrupt companies' production plans. The Agency has thus decided to define control periods as overlapping between the freeze and 20 percent reduction stages if the Protocol enters into force on a date other than January 1. Should the Protocol parties decide on a different approach to control periods, however, EPA will change its definition accordingly.

b. Controlled substances. Consistent with the Montreal Protocol, EPA initially proposed defining this term as "any substance listed in Appendix A to this Part, whether existing alone or in a mixture, but excluding any such substance or mixture that is in a manufactured product other than a container used for the transportation or storage of the substance listed."

A number of firms that responded to EPA's data collection rule (§ 82.20) found this definition confusing, and as a result, EPA included in its May 24 supplemental proposal further clarification. This clarification attempted to better distinguish "bulk" CFCs or halons from CFCs or halons contained in products; the Protocol drafters and EPA intended that only bulk CFCs and halons be subject to the freeze and reduction requirements. For example, while CFCs contained in a refrigerator are clearly not covered by the definition of controlled substances, it is less clear whether CFCs contained in small cans used to refill a car air conditioner would be considered in bulk form and thus a controlled substance or contained in a product and thus not a controlled substance.

Technical experts called together by UNEP to discuss implementation of the Protocol (Nairobi, January 1988) recommended that the Protocol's definition be clarified as follows: "Any amount of a [listed] substance or a mixture of [listed] substances which is not part of a use system containing the substance is a controlled substance and not a product containing a controlled substance [for the purpose of the Protocol]. If a [listed] substance or mixture must first be transferred from a bulk container to another container, vessel or piece of equipment in order to realize its intended use, the first container is in fact utilized only for storage and/or transport and the [listed] substance is considered [in] bulk [form or a controlled substance] and not a product". Under this modified definition, for example, CFCs in small cans used to refill refrigerators and car air conditioners would clearly be in bulk form and therefore be counted as controlled substances. EPA concluded that this clarification captured the bulk-versus-product distinction the Protocol drafters had sought to make, and proposed in its May 24 supplemental notice to add the clarification to the rule's definition. Comments on that notice supported the proposed clarification, and it has been incorporated into the final rule.

EPA also addressed the need for 'rules of thumb" in determining whether an ozone-depleting substance was in bulk form and thus a controlled substance. In reviewing the data submitted for purposes of calculating company-specific allocations, the Agency found that importers and exporters of CFC-113 in small containers did not always know the use to which the containers were ultimately put. EPA developed a "one gallon rule" to decide whether the reported CFC-113 was a controlled substance or not if the use of the container could not be determined; if the container of CFC-113 was under one gallon in size, the Agency assumed it was used for direct cleaning and thus not a controlled substance. EPA stated that for purposes of implementing the proposed rule, it would use the one gallon rule where the use of a container of CFC-113 was not known, and suggested that it might develop other rules of thumb as circumstances warranted.

Commenters supported EPA's rule of thumb for CFC-113 and suggested that it be extended to metric containers equivalent to one gallon in size and to other chemicals. EPA agrees that its one gallon rule should apply to containers that are approximately 4 liters in size. It also agrees that the rule should be applied to small containers of controlled substances other than CFC-113, but also only when the use to which those containers will be put cannot be determined.

As several commenters recommended, EPA intends to establish a process by which industry could seek further clarification of the definition as new ambiguities arise and by which the Agency would develop any other rules of thumb.

c. Export/Import. The December 14 NPRM and final rule (§ 82.20) defined export as "the transport of controlled substances from within the United States or its territories to persons or countries outside the United States." Several respondents raised issues concerning specific applications of that definition. Several questioned whether shipments of controlled substances to United States military bases abroad should be counted as exports. Others questioned whether controlled substances used on-board ships were to be considered exports.

As part of its May 24 NPRM, EPA proposed that in both cases the controlled substances *not* be considered exports. In the case of shipments to United States military bases abroad, the United States is clearly the beneficiary of the controlled substances and should count them toward its consumption limit. In both cases, it is unlikely that any other nation would claim them as imports. As a result, failure to include them as part of United States consumption would likely result in undermining the effectiveness of the Montreal Protocol by allowing some subset of controlled substances to remain unclaimed and unreported by any nation as consumption. Comments on this provision generally supported the clarification proposed on May 24.

For the reasons mentioned above, EPA has revised the definition of exports to specifically exclude shipments to United States military bases and to ships for on-board use.

In its May 24 supplemental proposal, EPA also discussed the potential export and import of recycled or used controlled substances. EPA explained that the Nairobi technical experts group had suggested that production be defined in the Protocol to exclude recycled substances but that export and import be defined to include them. The Agency noted that its definition of production already excluded recycled controlled substances, and described how its consumption allowances would allow import of used controlled substances and export of recycled substances.

Several commenters agreed that recycled and used controlled substances should be included in the definition of export and import. They noted, however, that not all used substances could be recycled, so that consumption allowances expended to import used substances would not be completely replaced by consumption allowances granted upon proof of export of the recycled used substances. They accordingly recommended that consumption allowances be required only for that portion of used substances that could be recycled. Another commenter instead argued that agreements between nations to recycle would be facilitated if the Agency's rule did not cover used or recycled controlled substances at all.

Since preparing the May 24 supplemental proposal, EPA has realized that defining export in its rule to include recycled *and* virgin controlled substances would risk United States noncompliance with the Protocol. Since the Agency's rule defines production to exclude recycled controlled substances, firms could recycle those substances without expending production and consumption allowances. However, if export is defined to include recycled substances, on exporting the recycled substances firms would receive authorization to convert potential production allowances and consumption

allowances in the amount of the recycled substances exported. Thus, as a result of exporting recycled substances for which no production and consumption allowances were expended, firms would realize a net increase in production allowances (up to the 10 or 15 percent limit on potential production allowances) and consumption allowances. They could then use these additional allowances to produce or import and *sell domestically* controlled substances in excess of the amount the initial allocations authorized.

If this occurred, the United States would exceed its limits under the Protocol. EPA's rule allocates consumption allowances equal to United States 1986 consumption and allows firms to obtain additional consumption allowances only upon proof of export, so that total available consumption allowances never exceed the United States consumption limit under the Protocol. If firms could recycle controlled substances without expending production and consumption allowances, but obtain production and consumption allowances upon exporting the recycled substances, total consumption allowances would exceed the United States limit. EPA cannot permit this and still comply with the Protocol, so it has revised the definition of export to make clear that only virgin production is covered by that term. In addition, it has revised the provisions governing the availability of consumption and production allowances to specify that only exports of virgin production will entitle a person to additional allowances. Firms can continue to export recycled or used controlled substances, but will not receive additional consumption or authorization to convert potential production allowances.

At the same time, EPA believes that imports must be defined to include both virgin and recycled or used chemicals. The potential would otherwise exist for virgin controlled substances to be mislabelled as recycled or used chemicals so that they could be imported without consumption allowances. To ensure that the United States does not exceed its consumption limit by inadvertently importing virgin production that has been labelled recycled, the definition of import in EPA's rule must be and has been revised to include both types of production. The Agency realizes that by defining import and export differently in this way, the rule no longer allows producers to recoup consumption allowances expended to import used controlled substances for recycling with allowances granted upon export of the recycled substances. Depending on how this issue is addressed by the Protocol Parties, EPA will consider revising its rule so as to provide consumption allowances for export of recycled substances without risking United States noncompliance with the Protocol.

d. Exporter. The December 14 NPRM did not contain a definition of exporter, but simply referred to an exporter as the person who exported the controlled substance (proposed § 82.13(g)). The December 14 final action defined exporter also in terms of the movement of controlled substances from within the United States to outside the country (§ 82.20(a)(3)).

The lack of a specific definition created considerable confusion over who should be considered the exporter. Clearly defining the exporter is important for determining both who must comply with the final rule's reporting requirements (§ 82.13) and who will obtain upon proof of export consumption allowances and authorization to convert potential production allowances to production allowances (§§ 82.10 and 82.11).

In its May 24 supplemental NPRM, the Agency proposed to define exporter as the person or company that enters into a contract to sell controlled substances to a person or company located outside the United States for use outside the United States. EPA believed the persons meeting this definition would likely have knowledge of the Agency's reporting requirements and incentive to seek the additional allowances available upon proof of exports. While commenters generally supported this approach, one chemical company pointed out that this definition fails to cover transactions between subsidiaries of multinational corporations that do not entail contracts of sale. Taking this comment into consideration, the Agency has modified its definition of exporter to "the person who contracts to sell controlled substances for export or transfers controlled substances to his affiliate in another country."

e. Importer. EPA did not directly define importer in either the December 14 NPRM or the final rule published on December 14. Instead, in the final rule EPA referred to importers as "persons who transported the chemicals listed in § 82.20(b) from outside the United States or its territories to persons within the United States or its territories." The December 14 NPRM also referred to an importer as "any person who imports controlled substances" (§ 82.13(f)).

Public response to both of these notices suggested that it was not clear who EPA considered to be the importer. The definition of importer is important because it determines who receives the initial allocation of consumption rights (§ 82.6), who is required to submit reports to EPA (§ 82.13(f), and who must hold consumption rights to authorize the importation of controlled substances (§ 82.4).

In its May 24 supplementary proposal, EPA proposed to define importer for the purpose of allocating consumption rights as "the first United States owner who is a supplier to or a member of the domestic industry that uses the controlled chemicals." EPA stated that this definition would generally result in consumption rights being allocated to the "importer of record" on United States Customs documents (the party responsible for obtaining a shipment's legal entry in the United States). However, in the few cases where the importer of record was a transfer or shipping agent and not the first United States' owner, the definition would mean that the first United States purchaser of the imports who was a member of the producer or user industry would receive the consumption rights allocation. EPA considered this definition appropriate not only because it would result in consumption rights being allocated in every case to members of the CFC and halon producer or user industries, but because it also provided a reasonable and rational basis for resolving which of two parties claiming 1986 imports should receive the applicable consumption allowances.

During the public comment period for the May 24 proposal, EPA identified another competing claim that was different from those it had considered in developing the proposed definition of importer. This claim involved, on the one hand, the shipments' importer of record which is a member of the domestic user industry and, on the other, the shipments' first United States owner (based on submitted invoices) which is a foreign producer's subsidiary. In the case of the competing claims discussed in the May 24 NPRM, application of the proposed definition always resulted in the claim being awarded to the importer of record, unless the importer of record was not a supplier to or member of the domestic user industry. However, in the case of the recently identified competing claim, the proposed definition would identify the foreign producer's subsidiary even though it was *not* the importer of record.

EPA had explained in the May 24 NPRM that it preferred its proposed

definition in part because it would result in the importer of record being awarded the claim except where a mere shipping agent was the importer of record. The Agency thought this result appropriate because the importer of record was legally responsible for obtaining the shipment's entry into the United States, and because in most cases shipments claimed by importers of record were *not* also claimed by anyone else.

On further reflection, EPA has concluded that its proposed definition reasonably resolves competing claims even though in the case described above, its application will result in a claim being awarded to a supplier to the domestic user industry that is *not* an importer of record. Given the many different ways import transactions can be configured, defining importer as the person who paid the foreign producer for the shipment (i.e., "the first United States owner") is both simple and logical. The first United States owner can in every case be considered to have "caused" the import since it paid the foreign producer for the shipment. To define the importer as the United States firm that placed the order with the foreign producer, as some commenters suggest, would extend the chain of causality which could arguably be extended further. For example, the customers of that United States firm could also argue that they "caused" the import by creating the demand. EPA has also come to appreciate that what firm is the importer of record may often be a matter of proximity to ports and thus an accident of convenience, or of a business relationship independent of the sale of the control substances.

Where two firms claimed to be the "first United States owner," EPA resolved the dispute in favor of the firm that paid the foreign producer for the imported chemicals, as indicated by submitted invoices. One commenter argued that payment to the foreign producer was not dispositive of ownership, and that the nature of the relationship between the producer and its United States subsidiary is also relevant. It specifically recommended that if the two firms are principal and agent or consignor and consignee, EPA should not consider the subsidiary an owner even if it paid its parent company for the shipment.

While the commenter's suggested application of the "first United States owner" definition might be plausible, EPA notes that it has discretion in applying terms of its own creation. The Agency chose the "first United States owner" definition in part because of its administrative simplicity. It likewise applied that definition in a straightforward manner—who paid the foreign producer—to preserve the advantage of simplicity. The commenter's suggested application would have required EPA to determine the legal relationship between firms and the significance of that relationship for the concept of "ownership," and undertaking which the Agency has neither the time nor resources to complete. EPA believes its application of its definition is reasonable under the circumstances.

In defining importer for allocation purposes and applying that definition, EPA is faced with assigning valuable allowances based on actions taken in the past with no awareness of their future significance. Any choice the Agency makes will thus seem inequitable to the firms whose claims are rejected in EPA's resolution of competing claims. EPA considered dividing claims between competing firms, but rejected this approach because there was no assurance that this approach would satisfy the firms involved. Moreover, the many firms that could have, but did not, submit competing claims would likely assert that, in light of an Agency decision to divide up competing claims, they should have the opportunity to submit those claims now.

The Agency also rejected one commenter's request that it conduct evidentiary hearings to determine who "most" caused an import to occur. First, EPA already has the information such hearings would be likely to provide. Second, what weight to give what factors (e.g., who placed the order with whom, who supplied what aspects of the transportation) would entail only more linedrawing that could be second-guessed any number of ways. Third, conducting such hearings would be administratively burdensome and, by delaying completion of the rule, could jeopardize the United States' ability to comply with the Protocol.

The Agency regrets that it could not honor all firms' import claims. However, the competing claims left EPA with no practical choice but to define importer in a manner that would identify only one firm. It believes its proposed definition is reasonable for the reasons given above, and has thus adopted that definition for purposes of allocating consumption allowances based on 1986 imports.

In the May 24 NPRM, EPA also indicated that it was considering defining importer differently for purposes of enforcing the rule's prohibition against importing controlled substances without consumption allowances. EPA expressed concern that as an ongoing matter, it may be administratively burdensome to determine who is the first United States owner and who is a supplier. It stated that requiring a shipment's importer of record to hold the consumption allowances authorizing the shipment would be easier to implement, and that purchasers of those shipments would be likely to ensure that the importer of record held the necessary consumption allowances.

Several commenters indicated that they would prefer that the first United States owner definition used for allocating consumption allowances also be used to determine who should hold consumption allowances authorizing an import shipment. However, one of these commenters suggested that the importer of record, where different from the first United States owner, also be required to report the shipment.

Notwithstanding these comments, EPA still favors defining importer as the importer of record for purposes of enforcing the rule's requirements. That definition avoids the potential for EPA becoming entangled in disputes between companies as to who is the first United States owner and who is a supplier to the user industry. It also avoids the need to require both the first United States owner *and* the importer of record to report the shipment. With advance knowledge of this definition, firms can decide wether they should be the importers of record for future shipments or should make arrangements with other companies to ensure that shipments are covered by the necessary consumption allowances.

EPA notes that the final rule defines importer only as the importer of record. Since the rule specifies firms' consumption allocations, there is no need for the definition of importer underlying those allocations (i.e., the first United States owner) to appear in the rule. The importer of record definition is included in the rule because it determines who is subject to the rule's prohibition against importing controlled substances without consumption allowances.

f. Production. The December 14 NPRM defined this term as "the manufacture of a controlled substance from any raw material or feedstock chemical; however, production does not include the manufacture of controlled substances that are used and entirely consumed in the production of other chemicals."

The public comments on the December 14 NPRM raised several

issues related to this definition. In addition, at the Nairobi meeting of technical experts, other nations suggested modifying the definition of production in the Montreal Protocol ("the amount of controlled substances produced minus the amount destroyed by technologies to be approved by the parties") so that reprocessed or recycled controlled substances would not be counted as part of a Party's production. The technical experts group agreed to suggest modifying the definition in the Protocol to state that production equals total production, including reprocessed and virgin chemicals, minus purchases of controlled substances for purposes of recycling. This definition would permit recycled controlled substances from one nation to be mixed with virgin production from another nation without the latter nation having to count the recycled portion as part of its production.

EPA explained in its May 24 supplemental NPRM that its definition of production, which is limited to manufacture from raw materials or feedstock chemicals, already excludes the portion of any output that results from reprocessed controlled substances. As a result, EPA proposed not to alter this aspect of its definition of production and commenters agreed that no alteration was necessary. The Agency has thus adopted the definition of production proposed in its December 14 NPRM.

Another issue related to the definition of production concerns the definition's exclusion of "controlled substances that are used and entirely consumed in the production of other chemicals." In its May 24 supplemental NPRM, EPA discussed the need to clarify limits on the use of this exclusion. Specifically, the Agency proposed that, because of potential administrative burdens and problems of verification, this exclusion would be limited to transformation of controlled substances that are produced and transformed by the same company. Thus, one company could not buy a controlled substance from another company and receive credit against its production by transforming that controlled substance. Nor could a company in the United States receive credit for transformation of a controlled substance produced in another country. EPA proposed to modify its definition of production to specifically include this limitation.

Four chemical companies commented that such restrictions would unduly limit the use of controlled substances as chemical feedstocks. They suggested that the producing and transforming firms could report and document any such transformations, and that the feedstock producers should receive credits. One commenter also argued that the proposed limitation would prevent companies that are not producers from entering into a business that uses controlled substances as feedstock.

The Agency notes that the proposed limitation would not prevent companies that do not produce feedstocks from purchasing feedstocks from producers. Also, it is not clear to EPA that small companies would be disadvantaged in competing against fully integrated companies, since their ability to purchase feedstocks will depend on future prices of controlled substances and the availability of product and chemical substitutes.

In any event, EPA believes that granting production credits for feedstock transformation involving two companies raises several difficult issues that require further study. One issue is which company should receive the production credit—the company which produced the feedstock or the company which transformed it. Similarly, the group of technical advisors to the Protocol could not agree on which country should be granted production credits in the case of feedstocks traded between countries.

There are also documentation issues. If the company transforming the feedstock is not the company receiving the credits, the transforming company would seem to have little incentive in maintaining accurate records. More generally, quantifying and verifying the amount of feedstock transformed and tracking the transfer and use of transformation credits would add layers of complexity to the Agency's compliance monitoring task.

These issues are even more difficult to resolve where transformations involve controlled substances produced in another country. Because of these concerns, EPA has decided to initially limit credit to production and transformation of feedstocks by the same company and will evaluate the possibility of expanding this provision in the future.

A third issue related to the definition of production involves EPA's decision in the December NPRM (see footnote 6 on page 47501) not to initially provide production credit for the destruction of controlled substances as the Montreal Protocol permits. (Under the Protocol, CFCs and halons destroyed by technologies to be approved by the Parties would not be counted as production). EPA stated that since no destruction technologies had yet been approved by the Parties it was deferring implementation of this provision, but that "EPA intends to work closely with industry in the future to review existing and new destruction technologies and, if appropriate, submit these technologies to the Parties for their approval."

Six chemical producers and users urged EPA to define production to reflect this destruction credit provision in its final rule as a means of encouraging the rapid development and implementation of destruction technologies. EPA agrees that efforts should be made to further development of destruction technologies. However, regardless of what it now includes in the rule, EPA will have to modify the rule to specify any destruction technologies once they are approved by the Parties, as well as reporting and recordkeeping requirements adequate to monitor their implementation. Thus, the Agency believes that modifying its definition of production when the Parties approve technology will be more efficient. In waiting to do so, the Agency will also benefit from the experience gained under the rule until that time.

Firms with potential destruction technologies are encouraged to expeditiously develop these technologies and to work with EPA to gain their approval by the Parties. EPA fully intends to modify its rule to allow for the grant of production credits as soon as destruction technologies are approved.

3. Prohibitions (§ 82.4)

The prohibitions section of the rule stipulates that no person may produce controlled substances at any time during any control period in excess of the amount of unexpended production allowances held by that person at that time, and that no person may produce or import controlled substances at any time during any control period in excess of the amount of unexpended consumption allowances held by that person at that time. It further specifies that both valid unexpended production and consumption allowances are required for production, while only valid unexpended consumption allowances are necessary for the importation of controlled substances.

The proposed rule specified that a person must "own" or "hold" production and consumption allowances to produce or import controlled substances. The final rule instead requires that allowances "held by that person under the authority of this Part" be sufficient to cover that person's production or import. EPA made this change to clarify its intention to only credit persons with production and consumption allowances

that the Agency's records show they possess or that the person has properly obtained by the means specified in the regulations. The Agency also sought to avoid having to determine who has legal ownership of allowances or becoming entangled in ownership disputes.

As explained in the December 14 NPRM, the use of both consumption and production allowances are required to ensure compliance with the consumption and production limits of the Montreal Protocol. One commenter suggested that EPA limit only production and not consumption, but if EPA does not limit imports as well as production, the United States could exceed the Protocol's limits on consumption, which is defined as production plus imports minus exports. EPA also sought through the use of consumption and production allowances to provide industry with the maximum flexibility available under the terms of the Protocol.

EPA received several comments on its proposed penalty which defined a violation in terms of "every kilogram" of production or importation in excess of unexpended production or consumption allowances. As explained in the December 14 NPRM, under section 113(b) of the Clean Air Act, penalties of up to $25,000 per day per violation can be assessed.

Several chemical producers generally believed that a penalty of $25,000 for each kilogram was excessive and impractical. They stated that given the nature of the process used to produce these chemicals, they cannot control or even measure production output to the level of a kilogram. One commenter stated that production output is measured based on storage in large holding tanks and therefore can only be measured with an accuracy of 1–2 percent. They argued that they should not be accountable for exceedances which they believed they could not accurately measure. In addition, these commenters suggested that EPA modify its rule to allow production overruns in one year to be compensated by a reduction in allocated allowances in the following year. A public interest group, on the other hand, supported EPA's proposed definition of a violation, stating that it would prevent significant "leakages" of controlled substances in excess of production and consumption limits.

In the time since its December NPRM, EPA has conducted several site visits to review the level of accuracy that producers can achieve in their production control and measurement, and the recordkeeping procedures they currently employ

The Agency recognizes that controlling the exact quantity of production is difficult and that measuring large quantities of controlled substances is subject to a small degree of error. However, the Montreal Protocol requires that Parties live within specified limits, and EPA has apportioned allowances that total to those limits. Were the Agency to define violations in units of 1,000 kilograms, for example, it would effectively license firms to exceed their limits by 999 kilograms. Were firms to take advantage of this flexibility, the United States would find itself in violation of the Protocol. Thus, EPA has adopted the provision that every kilogram of production or import in excess of valid unexpended production or consumption allowances is a separate violation of the rule.

Even though EPA has defined violation in terms of one kilogram, the Agency does not intend to necessarily seek the maximum statutory penalty for each violation. EPA intends to develop and administer a penalty policy that will effectively deter noncompliance, while at the same time recognizing that production of controlled substances cannot always be precisely controlled or measured. (The Agency notes that importers typically purchase controlled substances in kilogram units, so that they should be able to more precisely account for their shipments.)

In developing that policy, EPA will review potential price increases of controlled substances and estimate the penalty necessary to deter exceedences. The Agency will also consider the practical degrees of control in current production processes, the accuracy of measurements and industry recordkeeping in general, and the ability of EPA to monitor compliance. In assessing actual penalties, EPA will take into account these factors as well as the magnitude of the exceedence and the types of internal controls used by the firm.

EPA has also decided not to alter its prohibition provisions to allow producers and importers to exceed their allowances in one control period in exchange for a reduction in their allowances the next. The Montreal Protocol defines control periods in terms of 12 months and requires that controls be achieved during the 12-month period. Thus, the Protocol does not provide for the flexibility the producers seek, and EPA may not provide it without risking United States' noncompliance with the Protocol.

Section 82.4(d) implements the provision in the Montreal Protocol prohibiting Parties from importing controlled substances from nations not Party to or not complying with the Protocol beginning one year after the Protocol enters into force. No comments on this provision were submitted, but EPA requested and received comments on other possible trade provisions. Specifically, EPA requested comment on the desirability of moving forward in time implementation of the Protocol's provisions restricting the importation of products containing or produced with controlled substances from non-Parties. Eight commenters (chemical producers, user industries and public interest groups) urged EPA to take such action. However, most commenters generally urged EPA not to take action beyond that required by the Montreal Protocol, arguing that such action would be economically disruptive without improving environmental protection.

EPA does not believe that implementing trade prohibitions in tandem with the Protocol will adversely affect United States industry's ability to compete with companies from countries not Party to the Protocol in the early years following the agreement's entry into force. CFC and halon prices are not likely to increase significantly in the early years of the Protocol if firms act in a timely manner to employ cost-effective reductions. Moreover, most of EPA's major trading partners (e.g., Japan, Canada, Mexico, Western European nations) are likely to become Parties to the Protocol. However, EPA will continue to monitor this situation and may determine in the future that early implementation of trade restrictions against non-Parties is warranted.

4. Apportionment of Baseline Production Allowances (§ 82.5)

This section of the rule sets forth companies' baseline production allowances and the basis for calculating them. To determine these allowances, EPA in its December 14 final rule required producers of controlled substances to submit data documenting their production levels in 1986, the baseline year specified by the Protocol. After reviewing these data submissions for completeness and accuracy, EPA published a supplemental proposal on May 24 containing proposed company-specific allocations and clarifying the definition of relevant terms.

EPA proposed to calculate each producer's baseline allowances in three steps First, consistent with the rule's definition of production, the producer's 1986 production level of each controlled chemical was reduced by the amount of that chemical the producer used in 1986 to make other controlled substances.

Second, the producer's adjusted production of each controlled chemical from raw materials or feedstocks was multiplied by that chemicals' ozone depletion weight as set forth in Appendix A of the December 14 proposal to arrive at a "calculated level" of production. Finally, the resulting calculated levels were added together for Group I chemicals and for Group II chemicals. Firms that produced chemicals in both Group I and Group II were thus apportioned separate production allowances for Group I and Group II chemicals.

EPA received comments from one chemical producer on its December 14 NPRM opposing its proposed basis for calculating baseline production allowances. This producer suggested that, in the case of halons, EPA should use a 1987 base year to more accurately reflect current free market conditions. It also suggested that allocations for halons should be based only on "non-government" business to avoid providing a competitive advantage to past vendors who sold to the federal government, the single largest consumer of these chemicals.

The Agency does not agree with either comment. The Protocol specifies 1986 as the baseline year. EPA could only use a different year as a baseline and ensure compliance with the Protocol if it prorated 1987-based allowances so that they do not total to more than 1986 United States' production. To do this would entail EPA collecting and reviewing data for both 1986 and 1987, and otherwise complicate a process the Agency already found cumbersome. Moreover, use of 1986 as the baseline year is more equitable because firms may have changed their market behavior in 1987 in response to on-going Protocol negotiations. EPA also sees no compelling reason to distinguish past sales to the government (or any other large users) from any other past sales. As EPA defined and proposed it, the allocated quota system simply grandfathers past market shares. Since the rule permits allowances to be transferred, however, market shares may still change in the future.

In comments on the May 24 NPRM, firms generally agreed with their proposed production allowances. EPA reviewed the comments and is including final allocations in the final rule.

5. Apportionment of Baseline Consumption Allowances (§ 82.6)

To implement the Protocol's limits on consumption (defined as production plus imports minus exports), the calculation of baseline consumption allowances requires reducing the sum of production and imports by exports. Complications arise in attributing exports to producers and importers. In all other respects, consumption allowances are calculated in the same manner as production allowances.

In the December NPRM, EPA proposed to simply allocate exports to producers in proportion to their 1986 market share of production, since producers were responsible for most exports presumably in proportion to their share of the production market. In response to public comments questioning the equity of this approach, EPA proposed in its May supplemental NPRM to calculate each firm's consumption allowances by subtracting the amount of controlled substances that firm *directly* exported in 1986. Accordingly, importers as well as producers would have their consumption allowances reduced to reflect their direct exports. Since not all exports could be traced to a producer or importer, EPA also proposed to attribute the remaining exports to producers in proportion to their 1986 market share of production. In addition, EPA stated that because the final rule would contain the company-specific apportionments, it would omit from the final rule the explanation of how they were calculated.

Several firms urged EPA to take additional steps to trace exports back to their original producer. EPA concludes that it would be impractical and in many cases infeasible to undertake such an exercise. To verify claims of consumption allowances, the Agency examined large volumes of supporting documentation and in some cases corrections were made to the claims. EPA believes that a similar verification process requiring supporting documentation would be required to assign the unattributed exports to producers and importers. Further, EPA would have to obtain the exporter's proof of purchase from a producer or importer to assign these unattributed rights appropriately. Although providing the necessary documentation might be relatively easy for some firms, for others it would be difficult and in some cases even impossible. Where exporters bought CFCs from multiple sources, adequate documentation to determine the sources of particular exports simply does not exist. Given how little time remains before the Protocol is due to enter into force and the infeasibility of tracing all exports, EPA has decided against attempting to further attribute currently unattributable exports.

Two commenters complained that use of the proposed correction factor would unfairly penalize producers that had produced little or no controlled substances for direct or indirect export. They suggested that EPA allocate the unattributed exports in proportion to a firm's direct exports rather than production. EPA disagrees with this approach. The Agency does not believe that there is any correspondence between a manufacturer's share in the direct export market and that manufacturer's share of the non-producer exports since exporters could have purchased from any of the producers in the marketplace. The Agency also cannot be certain that exporters did not purchase any controlled substances from the producers who claim not to have contributed even indirectly to the export market. To verify such claims, EPA would have to trace potentially long chains of sales and resales, which the Agency has neither the time nor resources to do. As a result, EPA believes that the apportionment of unallocated exports based on production share is a more equitable approach.

Another commenter noted that it exported a chemical it did not produce and thus argued that it should not have the export of that chemical subtracted from its consumption allowance. It likened its exports to those of exporters who are neither producers nor importers and whose shipments have consequently been placed in the unattributed exports pool for allocation to producers by means of the correction factor.

EPA agrees with this commenter. In calculating consumption allowances, the Agency sought to attribute exported chemicals to those firms that were responsible for the production or import of the chemicals. In the case of this commenter and two other firms that EPA identified based on information submitted in response to the December 14 final rule, the Agency subtracted from their proposed consumption allowances exported chemicals of a type they neither produced nor imported. EPA has thus placed those exports in the unattributed export pool and modified producers' consumption allowances accordingly.

As discussed above, the Agency has decided to require consumption allowances for import of used controlled substances for recycling. EPA thus considers it appropriate to allocate firms' consumption allowances in the amount of any 1986 import of used controlled substances, so that they may continue to engage in recycling without having to purchase consumption allowances that could otherwise be used

to produce or import virgin production. EPA identified one firm that imported used controlled substances in 1986 and has increased that firm's consumption allowance accordingly

6. Grant and Phased Reduction of Baseline Production and Consumption Allowances for Group I Controlled Substances (§ 82.7)

This section of the rule implements the Protocol's phased reduction of CFCs (Group I controlled substances). It grants companies decreasing percentages of their baseline production and consumption allowances in step with the Protocol's three-stage reduction schedule. Following entry into force of the Protocol, companies are granted 100 percent of their baseline allowances for the control periods during which the Protocol requires a freeze in production and consumption of Group I controlled substances. (As stated earlier, once EPA knows the date of entry into force, it will publish a **Federal Register** notice giving the dates of the control periods for the freeze and subsequent stages.) As of July 1, 1993, companies are granted 80 percent of their baseline allowances for each control period and as of July 1, 1998, 50 percent of their baseline allowances.

As described earlier, should the Protocol not enter into force on January 1, 1989, the first control period would not begin on July 1, 1989. In that event, EPA intends to implement the Protocol's 12-month control periods by having overlapping periods during the transition from the freeze stage to the 20 percent reduction stage. EPA has accordingly modified the rule to grant 100 percent of 1986 baseline levels for each of the control periods which "begins" before July 1, 1993, instead of "ends" before July 1, 1993. The only effect of this change will be to allow the last 12 month control period of the freeze to continue beyond July 1, 1993, if necessary. Of course, firms will also have to meet the 20 percent reduction requirement for the 12-month period beginning on July 1, 1993.

One chemical producer raised an additional issue concerning the timing of control periods. While recognizing that EPA's regulation cannot accomplish this goal, it suggested that the Protocol be modified to shift control periods to calendar years. EPA notes, however, that agreement on the timing of the staged reductions was reached only after considerable negotiations and only just before the Protocol was signed. As a result, EPA strongly believes that, notwithstanding the minor inconvenience that may result from the use of 12-month periods which are not coincident with the calendar year, reopening this issue at this time is inappropriate. However, the issue of stringency and timing of controls will be reviewed by the Parties under Article 6 of the Protocol at which time this issue can be further addressed.

7. Grant and Freeze of Baseline Production and Consumption Allowances for Group II Controlled Substances (§ 82.8)

This section implements the Protocol's freeze of the production and consumption of halons (Group II controlled substances). It grants companies 100 percent of their baseline production and consumption allowances for the control periods specified in § 82.3(f)(2). Section 82.3(f)(2) is reserved for future determination by EPA, because the Protocol provides for the halon freeze to begin on the first day of the thirty-seventh month following the Protocol's entry into force. Assuming the conditions required for entry into force are satisfied by January 1, 1989, the restrictions on halons would take effect on January 1, 1992. If entry into force is delayed, the freeze on halons would also be delayed. EPA will publish the dates of control periods for Group II controlled substances soon after the date of entry into force has been determined.

8. Availability of Production Allowances in Addition to Baseline Production Allowances (§ 82.9)

This section implements provisions in the Montreal Protocol which allow for limited production (but not consumption) increases above limits described above. At each stage, the Protocol allows production levels during a control period to exceed the limit by no more than ten percent (or 15 percent when CFCs must be reduced by 50 percent) of the 1986 level. Such increases are permitted "only so as to satisfy the basic domestic needs of the Parties operating under Article 5 [special situation of developing countries] and for the purposes of industrial rationalization between parties." Industrial rationalization is defined by the Protocol as "the transfer of all or a portion of the calculated level of production of one Party to another, for the purposes of achieving economic efficiencies or responding to shortfalls in supply as result of plant closures." The Protocol also allows a Party to exceed its production limit to the extent it reaches a binding agreement with a Party which produced less than 25 kilotonnes of controlled substances in 1986, if the "25-kilotonne Party" will reduce its production allowance by the same amount.

To enable producers to increase their production to the extent permitted by the Protocol, § 82.9 grants to each firm receiving baseline production allowances under §§ 82.5 and 82.6 "potential production allowances" equalling 10 or 15 percent of their baseline allowances depending on the control period and group of controlled substances. Holders of potential production allowances may then obtain EPA authorization to convert them to production allowances under § 82.11 by proving they exported to Parties a calculated level of controlled substances equal to the amount of potential production allowances they want to convert, or under § 82.12 by obtaining such authorization from another firm that obtained the authorization under § 82.11. In addition, § 82.9 permits anyone to produce controlled substances to the extent they receive a transfer of a 25-kilotonne Party's production allowance and they demonstrate to EPA that the transfer is *bona fide*.

One chemical producer suggested EPA should grant potential production allowances based on producers' past export activity. This producer argued that to be equitable, an allocated quota system should rely on past activities as the basis for granting all allowances including any potential production allowances. EPA believes that *past* export activities are properly dealt with in the context of calculating baseline consumption allowances and should not be used as a basis for allocating potential production allowances. To do so would unnecessarily link future export activity to past activity. Since any controlled substance produced could be exported, total production is a more appropriate basis for allocating potential production allowances. As a result, the rule provides that potential production allowances are allocated on the basis of total production allowances and not on the basis of past exports.

Another chemical producer suggested that the 10 percent limit on potential increases in halon production was too low because only a few relatively large production plants exist throughout the world and any industrial rationalization would necessarily have to involve increases greater than 10 percent. The commenter recognized, however, that any changes in the allowable increases would require modification of the Protocol. EPA is concerned that allowing halon production increases of more than 10–15 percent for the purposes of industrial rationalization would further concentrate production in a few

countries and create problems of potential monopoly power.

A public interest group stated that EPA should take action to ensure that any added production exported "to supply the basic domestic needs" of developing countries who qualify under Article 5 of the Protocol is used only for such needs and not reexported either as bulk chemicals or in products produced with or containing these chemicals. EPA believes that ensuring that Article 5 countries use imported CFCs and halons for their "basic domestic needs" is a Protocol enforcement issue within the purview of the Parties and not EPA. Since the Protocol does not define "basic domestic needs," EPA would risk placing inappropriate constraints on developing countries when the purpose of Article 5 is to encourage such countries to join the Protocol. EPA is also not equipped legally or financially to police how controlled substances are used in other countries. Compliance monitoring and enforcement issues are due to be taken up by the Parties at their first meeting within one year of the Protocol's entry into force and at that time implementation of the "basic domestics needs" provision can be addressed.

EPA also received several comments on its implementation of the industrial rationalization provision. A chemical company commented that EPA's was faithful to the intent of the Protocol negotiators that Parties be allowed to increase production somewhat in order to export controlled substances to other Parties. In contrast, a public interest group commented that production increased "for purposes of industrial rationalization" should be allowed only where the Party receiving the increase decreases its production by the same amount and where one of the two specified purposes—achieving economic efficiency or responding to shortfalls in supply as a result of plant closures—is being served.

The industrial rationalization provision of the Protocol is somewhat ambiguous, since at least two of its key terms could be interpreted in different ways. Industrial rationalization is defined in part as "a transfer of a calculated level of production between Parties." "Calculated level of production" could refer to the right to produce controlled substances or the produced controlled substances themselves. Similarly, "transfer" could refer to exchange of rights or simply trade in produced substances.

EPA has interpreted the industrial rationalization provision in light of the United States negotiators' understanding of the purpose of that provision. According to the lead United States negotiators, the industrial rationalization provision was included to permit some future flexibility in world markets for controlled substances. In 1986, the Protocol's baseline year, only a few nations were major exporters of controlled substances; a production cap based on 1986 levels with no allowances for limited growth would thus effectively lock in 1986 export-import relationships until substitute chemicals were available. By allowing some increase in Parties' production levels, the Protocol negotiators hoped to facilitate future competition in the world market.

EPA has thus interpreted the terms of the industrial rationalization provision mentioned above to mean trade in controlled substances between Parties. The Agency notes, moreover, that because the Protocol does *not* allow for any exceedence of Parties' consumption limits, trade in controlled substances effectively results in a transfer of production rights after 1992. Under the Protocol, Parties may not import controlled substances from non-parties beginning one year after the Protocol enters into force, and exports to non-Parties may not be subtracted in calculating a Party's consumption level as of January 1, 1993. Thus, the Protocol in effect creates a Party wide "bubble" of controlled substance production. If one Party increases its production by the 10 or 15 percent allowed, it must export that to a Party or decrease its imports from Parties to stay within its consumption limit. The Party that imports the increased production or loses the export of its own production will, in turn, have to decrease its own production (or export it to another Party) in order to stay within its consumption limit. Thus, a transfer of production rights can be said to have occurred.

EPA finds further support for its interpretation in the contrasting Protocol provision for transfers involving 25-kilotonne Parties (Article 2, paragraph 5). That provision expressly provides that the total combined calculated levels of production of the Parties involved in the transfer concerned cannot exceed production limits imposed by the Protocol and that the Protocol Secretariat be notified of any such transfer. The industrial rationalization provision contains no similar requirement that a production increase by one Party be offset by a production decrease by another

The Agency does not believe it is necessary to require firms engaging in industrial rationalization to prove that they are doing so for the specified purposes. Economic theory suggests that in a free market, agreements to buy and sell are based on what the participants consider to be in their economic self interest. A firm's decision to export its production is thus by definition "economically efficient," one of the two purposes industrial rationalization is to serve.

While EPA believes that it has correctly interpreted the industrial rationalization provision, if the Parties to the Protocol clarify this provision in a manner inconsistent with EPA's interpretation, the Agency intends to modify its rule accordingly.

EPA received three comments from chemical producers that it had unnecessarily limited production transfers with 25-kilotonne Parties to those involving transfers to the United States, whereas the Protocol allows transfers of production both to and from 25-kilotonne Parties. EPA has modified its final rule to allow for this added flexibility. However, in the case of transfers of rights to 25-kilotonne Parties, EPA recognizes that interests beyond the narrow commercial ones of the involved firm may be at stake. For example, transfers may adversely impact domestic industry and may have broader trade implications. As a result, EPA has reserved the right to review and approve any proposed transfers of production rights to entities outside the United States.

Any trades occurring under this transaction are also limited in size because EPA believes that the Protocol negotiators did not intend 25-kilotonne Parties to exceed the 25-kilotonne ceiling as a result of the transfer. The Protocol negotiators were concerned that under the agreement's reduction schedule, it would become uneconomic for low-producing Parties to continue production. They therefore provided that Parties with less than 25-kilotonnes of production in 1986 could transfer their production rights to another Party that could produce controlled substances economically, or receive transfers of rights so that they could maintain economic production levels. They did not intend to allow 25-kilotonne Parties to actually *increase* their production capacity as a result of buying rights, but to make use of other Parties' existing capacity or their own. (This approach is consistent with that taken to developing countries; negotiators allowed Parties to increase their production in order to supply developing country Parties and obviate the need for developing countries to build further production facilities.) Accordingly, EPA will only approve transfers to 25-kilotonne Parties that do not result in the Party's total

production rights exceeding 25 kilotonnes.

9. Availability of Consumption Allowances in Addition to Baseline Consumption Allowances (§ 82.10)

Under this section, firms may receive additional consumption allowances upon proof of export of controlled substances. This provision is consistent with the Protocol's definition of consumption as production plus imports minus exports. EPA apportioned baseline consumption allowances equal to 1986 production plus 1986 imports minus 1986 exports. As a result, if the United States exported no controlled substances after the Protocol takes effect, it will still be in full compliance with the Protocol. Accordingly, to the extent controlled substances are exported, additional consumption allowances can be authorized without violating the consumption limits established by the Protocol.

In the initial years of the Protocol's operation, additional consumption allowances will be issued for all exports. However, the Protocol provides beginning on January 1, 1993, exports of controlled substances to non-Parties shall not be subtracted in calculating the consumption level of the exporting Party. To reflect this limitation, § 82.10(b) prohibits the grant of additional consumption allowances for exports to non-Parties also beginning on January 1, 1993.

Seven commenters (chemical producers and a trade association) stated that EPA had unnecessarily restricted the issuance of additional consumption allowances until exports had been received in the country of destination. They suggested that EPA instead consider a shipment an export when it departs the United States so that additional allowances for the shipment could be obtained much sooner. Since additional consumption allowances and authorizations to convert potential production allowances to production allowances can only be used during the control period in which they are granted, any significant lapse of time between shipment and the grant of allowances would substantially undermine the ability of firms to obtain and use these rights, particularly during the last quarter of a control period. These commenters argued that granting allowances at the time of export would not create a loophole (e.g., controlled substances not counted by any nation) as long as all nations agree that exports would be counted at the time of departure and imports at the time of arrival. The technical experts at the Nairobi meeting similarly recommended that a shipment should be considered an export at the time it leaves the country of origin. EPA has decided to grant consumption allowances and authorization to convert potential production allowances upon proof that controlled substances have been shipped from the United States, on the assumption that the other Parties will also consider a shipment an export upon its departure and an import upon its arrival. Such a uniform approach, which the technical experts group has recommended, will permit adequate monitoring of Parties' compliance. However, if the Protocol Parties do not adopt the technical experts' recommendations, EPA will reconsider its treatment of this issue.

Three commenters (one chemical producer and two halon users) also requested that EPA specify a time limit in which it will process requests for additional consumption allowances and other administrative reviews. EPA is not now in a position to accurately assess the time it will require to process applications, but will endeavor to minimize any delays in reviewing and acting on such applications. It will consider at some later date, as part of its operating procedures, establishing a goal for timely processing of applications.

Two chemical producers suggested that exporters be allowed to credit themselves with additional consumption allowances and conversion authority upon exporting and that EPA should monitor these exporters' activities by conducting an annual audit of each firm. EPA cannot accept this suggestion because it would create far too much uncertainty as to whether a particular export qualified for additional allowances and thus whether the United States was complying with the Montreal Protocol. EPA also believes that an affirmative decision by EPA on each application for additional allowances would reduce the possibility of fraud and provide greater market certainty for future transactions involving production and consumption allowances.

10. Exports to Parties (§ 82.11)

This section sets forth the process by which any person may export controlled substances to another Party to the Protocol and obtain from EPA authorization to convert potential production allowances to production allowances. The authorization will only be valid during the control period in which it is issued. Requests for authorization to convert will also be considered a request for additional consumption allowances under § 82.10.

Following the export of a controlled substance and receipt of authorization to convert potential production allowances to production allowances, the recipient has two options. If the person holds potential production allowances (issued under § 82.9), he may use his conversion authorization to produce controlled substances consistent with § 82.11 or, if he does not hold potential production allowances, he may transfer his conversion authorization under § 82.12 to a person that does. In keeping with the Protocol, EPA's rule sets a 10 percent limit on potential production allowances for the freeze and 20 percent reduction stages for Group I and Group II controlled substances and a 15 percent limit for the 50 percent reduction stage for Group I chemicals.

As discussed above in the context of the issuance of additional consumption rights (§ 82.10), several commenters requested that EPA consider a shipment an export when it leaves this country, instead of when it arrives in another. EPA has modified the rule to allow for exports to be counted at the time they leave the country. As a result, EPA has dropped that part of § 82.11 which requested, as part of the application for authorization, the date the shipment arrived at the foreign destination.

11. Transfer of Production and Consumption Allowances (§ 82.12)

EPA's proposed § 82.12 permitted the transfer of the allowances granted under this rule subject to certain procedural safeguards. This transfer section is reserved in today's final rule pending further review of the procedural safeguards. Even without the transfer provision, the regulation fully implements the Montreal Protocol. However, EPA recognizes that the transfer provision will make the rule more economically efficient. EPA expects to promulgate a final transfer provision in advance of the effective date of today's regulation.

12. Recordkeeping and Reporting Requirements (§ 82.13)

The December 14 NPRM outlined alternative reporting and recordkeeping requirements for producers, importers and exporters of controlled substances. Generally, EPA proposed that producers and importers maintain daily records of production or imports and submit monthly reports to EPA to monitor compliance. EPA also proposed that producers file and periodically update annual production plans for compliance purposes. Similarly, the Agency proposed that exporters report their

shipments on a monthly basis. In the December 14 preamble, EPA outlined several options of varying detail for reports and recordkeeping (52 FR 47504). In the discussion that followed those options, EPA stated that it was leaning toward requiring more detailed requirements to facilitate its monitoring of compliance.

Since the December 14 proposal, EPA has reviewed the comments on these reporting and recordkeeping requirements. In addition to these comments, EPA has met with the producers of controlled substances to discuss the reporting burdens of the proposed rule, and visited three plants to review current producer recordkeeping practices.

a. Producers. (1) Daily Recordkeeping—The December 14 proposed rule requested that producers maintain the following information: Daily records of the quantity of the controlled substances produced at each facility including controlled substances produced and consumed for feedstock purposes; daily records of the quantities of HCFC-22 and CFC-116 that may also be produced at the same facilities; continuous records of the reactive temperatures and pressures within the primary reactor and initial distillation column at each facility during the production operations; daily records of purchases and uses of specified materials consumed in producing the regulated chemicals; and daily records of the quantity and purchaser of controlled substances produced at each plant (Section 82.13(e)). The proposal required that these records be retained for a period of four years.

EPA requested daily records to obtain precise information on production as well as important independent checks for verification. These checks include the quantity of feedstock consumed in production and the volume of chemicals which could be produced within the same production unit (i.e., HCFC-22 and CFC-116), as well as sales of these chemicals. EPA believed that the more precise information would aid in verifying reported production and pinpointing violations.

Seventeen commentors believed that these daily recordkeeping requirements were unnecessary and excessive. Specifically, several commentors believed that such parameters as feedstock materials bought and used, records of sales volumes and customers, and reactor temperatures and pressure were unnecessary and in some cases meaningless as checks on production.

In reviewing the recordkeeping practices of producers, EPA found that much of the information required by the proposal is currently recorded on a daily basis by the industry. Since this information is already being recorded, EPA does not believe that a requirement for daily recordkeeping is excessively burdensome, and therefore maintains with modifications that requirement in the final rule. EPA recognizes that while continuous records of reactive temperature and pressure may provide a check on production, they would also entail detailed analysis for compliance monitoring when other information is available. For this reason, these parameters have been eliminated from the daily recordkeeping requirements. EPA has also eliminated the requirement for sales records which were to be maintained for each plant. In many cases, sales are recorded at the producer level but not at the plant level; based on its review, EPA believes that shipments serve as a better check on production. EPA has also eliminated recordkeeping requirements for the quantities of feedstocks purchased. Since these raw materials may be used in the production of chemicals other than controlled substances, purchase records may not provide a useful check on quantities of raw materials consumed for production of controlled substances.

For the final rule, producers are required to maintain dated records of the quantity of the CFCs and halons produced at each facility including the dated records of the quantity of controlled substances used as feedstocks in the manufacture of controlled substances and in the manufacture of non-controlled substances, any virgin, used or recycled controlled substances introduced into the production process of new controlled substances. They are also required to keep records of the following feedstock materials consumed in producing the regulated chemicals at each plant: Carbon tetrachloride, perchloroethylene, chloroform, hydrofluoric acid, chlorine, bromine, CFC-113; HCFC-22; and CFC-23. EPA requests records of feedstocks consumed since EPA can approximate the quantity of controlled substances produced by monitoring the materials consumed. Producers must also maintain dated records of HCFC-22 and CFC-116 produced within the same facility or production unit of a controlled substance. The production volume of HCFC-22 and CFC-116 will help determine the duration of time in which facilities are dedicated to the production of controlled substances if the plant maintains year round production. The Agency also requires records for the quantity of used or recycled controlled substances, the date received, and the names and addresses of the sources of recyclable or recoverable materials containing controlled substances which are recovered at each plant. EPA is also requesting that records of shipments of controlled substances from plants be maintained. This is a new requirement, recommended in discussion with industry, which is based on current practices and which EPA believes will aid the Agency in verifying production.

Based on a review of producer's methods of monitoring CFC and halon production, EPA believes that current methods of recordkeeping will generally be sufficient to satisfy the recordkeeping requirements. EPA is aware that some producers may not make daily production estimates over weekends, and that production may not be measured directly but determined from records of consumption, shipments, and inventories. EPA believes these accounting procedures are acceptable for purposes of this regulation, but needs to verify that currently maintained records are sufficient to comply with recordkeeping requirements. EPA is requiring producers to submit within 120 days of publication of this rule a report detailing how production is measured on a regular basis and how this data will be used to determine quarterly production figures in kilograms. Any change in accounting and measurement methods must be described and submitted to EPA within 60 days of the change. EPA reserves the right to require alternate measurement techniques if deemed necessary.

EPA has altered the requirement that these records be maintained from a period of four years to a period of three years. EPA believes that it may be necessary to review historical production records during investigations of potential violations and that three years of past activity should prove adequate for such review.

(2) Production Reports. In the December 14 proposal EPA requested monthly reports within 15 days after the reporting period from producers of the controlled substances for each plant and for all plants owned by the same company. EPA requested that the reports include summaries of monthly production of the controlled substances; quantities of HCFC-22 and CFC-116 produced that month at each facility; monthly summaries of the quantity of sales for each of the controlled substances; the quantity and source of material containing recoverable controlled substances and the quantity of controlled substances recovered; summaries of total monthly and control period-to-date production of the

calculated levels of Group I and Group II controlled substances; and the producer's total consumption allowances, production allowances and authorization to convert potential production allowances to production allowances.

In their comments, industry members argued that quarterly or annual reporting was sufficient, and that a 30- to 45-day filing period at the end of the reporting period was necessary. In addition, commenters believed that the reporting of unregulated chemicals was not required to measure compliance.

After consideration of these comments and based on meetings with producers and site visits, EPA has determined that quarterly reports with a filing period of 45 days after the close of the reporting period are appropriate. Quarterly reporting will provide EPA with periodic review of producer's compliance with the regulation during a control period and help target inspections while minimizing the reporting burden on producers. EPA has extended the filing period to 45 days to allow companies adequate time to review and verify their reports and to allow companies with more than one plant to compile the information into a single report. EPA has considered fiscal quarters rather than actual quarters. However, the Montreal Protocol does not allow EPA the flexibility to shift to fiscal control quarters.

Therefore EPA requires that producers report on a quarterly basis consistent with the applicable control period.

Since one purpose of these reports is to provide EPA with information to verify production, EPA requests that producers submit the following information: Summaries of quarterly production of the controlled substances, specifying the quantity used and consumed as feedstock for controlled and non-controlled substances; the quantity, the date received and source of material containing recoverable controlled substances and the quantity of controlled substances recovered; summaries of total quarterly and control-period-to-date calculated production levels of Group I and Group II controlled substances; and the producer's total expended and unexpended consumption allowances, expended and unexpended production allowances, potential production allowance, and authorization to convert potential production allowances to production allowances, as of the end of the quarter.

One change in the proposed reporting requirements involves reporting of the quantity of shipments from each plant for each of the controlled substances, instead of sales. This change has been made because shipments are a more accurate check than sales on production and records of these are currently maintained by producers. EPA has deleted the requirement that producers report the quantities of HCFC–22 and CFC–116 produced. This information is still required for recordkeeping purposes so that it can be reviewed during site inspections, but need not be included in reports to EPA.

(3) Annual Production Plan. EPA proposed in the December 14 NPRM that producers submit annual production plans for each facility and notify the Agency of any significant shifts in the location or quantity of production. EPA believed that such plans would provide useful information for monitoring compliance.

Industry members commented that the production plans are an unnecessary check on compliance. Furthermore, although firms are likely to develop an annual production plan for internal purposes, these plans rarely agree with actual monthly or quarterly production volumes. They also objected to the requirement that companies would need to notify EPA when production shifts occurred to meet demand shifts. EPA no longer believes that continual justification of production volumes with the production schedules in the production plan will assist it in monitoring compliance. For this reason, EPA has eliminated the annual production plan as a reporting requirement.

b. Importers. (1) Daily Recordkeeping—EPA proposed that importers maintain daily records of the quantity of controlled substances imported; the dates and ports of call for imports; the date and port of entry into the country; the dates on which and the country in which the imported controlled substances were produced; and a name of a person from whom additional information can be obtained. Similar to daily recordkeeping by the producers, EPA proposed daily recordkeeping by the importers to provide more precise information on import activities which would aid in evaluating trades and, pinpointing violations and allow comparison with U.S. Custom and Census data.

Comments on proposed daily records from importer's related primarily to the scope of items to be recorded. Because imports are now counted at the time they are received in a country, it is no longer necessary to know the date on which they were produced. For the same reason the Agency will not require the dates and ports of call for imports.

The final rule requires that importers maintain daily records of the following: the quantity of virgin used and recycled controlled substances imported; the date and port of entry into the United States or its territories; the country from which the imported controlled substances were exported and the port of exit. In addition, EPA requires importers to record the commodity code and his importer number for each shipment. Importers must also keep the following documentation to verify imports: the bill of lading, the invoice and U.S. Custom's Entry Summary Form (Form 7501). This information will allow EPA during compliance checks and investigations of potential violations to check U.S. Census reports against shipments. Retention of the bill of lading and the invoice is necessary to provide EPA with an independent check on quantities imported, separate from Census and Customs data.

(2) Monthly Reporting. EPA proposed to require importers to submit a monthly summary of the information recorded on a daily basis. In addition, monthly reports by importers were to include totals for control-period-to-date and the importer's total consumption allowances at the end of the month.

Commenters generally believed that monthly reporting is too frequent and that quarterly reporting would be sufficient. They also argued that a 30-day filing period after the close of the reporting period is needed to provide accurate reports to EPA.

For the final rule EPA requires that importers, like producers, file quarterly reports within 45 days of end of the reporting period. Importers may receive shipments at several ports throughout the country and 45 days are needed to collect this information. EPA believes that these companies need sufficient time to summarize the information and report accurate quantities. Also since several importers are also producers, the reporting period for importers should be consistent with the 45 day reporting period for producers. These reports must include the following: The quantity of controlled substances that are imported in that quarter; the calculated levels of Groups I and II controlled substances imported for the quarter and the total for the control period; the total quantity of expended and unexpended consumption allowances the importer holds at the end of the quarter. The importer must also provide a summary of his import activities which shall include the quantity of each import, the date and port of entry into the United States or its territories; the country from which the imported controlled substances were

imported and the port of exit; and a name and address from whom additional information can be obtained. In addition, the commodity code and his importer number have been included to assist with comparison and verification of importer records with U.S. Census and Customs records.

c. Exporters. EPA proposed that exporters who did not report under §§ 82.10 and 82.11 of the rule submit reports within one month of export which would include the name and address of the exporter and recipient of the export; the exporter's Employer Identification Number (EIN); the type and quantity of controlled substances exported; the date on which and port from which the exports were shipped; the date and country to which the exports were shipped; and the date and source from whom the exported controlled substance were purchased. EPA requested the information to provide a basis for independently verifying that exports were shipped.

EPA has modified these reporting requirements for exporters not requesting additional consumption rights under §§ 82.10 and 82.11. Firms not requesting additional consumption rights must report within 45 days of the end of the control period. EPA requires this information to comply with the Montreal Protocol and therefore does not believe that monthly reporting is necessary. Since consumption rights are not requested for these exports, periodic monitoring and independent verification is not needed. Consequently, these exporters need only report at the end of the control period.

From these exporters EPA requires the following: name and address of exporter and recipient of the exports, the exporter's Employer Identification Number (EIN); the type and quantity of controlled substances exported and the percent that is recycled or used; date and port from which the exports were shipped. The commodity code of the shipment is a new requirement which allows EPA to verify these shipments. Also, because exports are now to be counted at the time of their departure from this country instead of their date of receipt in a foreign country, EPA has eliminated the requirement that exporters report the date of a shipment's arrival in the receiving country. EPA has maintained the date and source from whom the exported controlled substance were purchased as a reporting requirement to ensure that in calculating its national consumption limit, only virgin controlled substances that are exported are subtracted from its total consumption.

EPA has added § 82.13(b) regarding the use of reports and records for purposes of compliance determinations to clarify the Agency's original intent that the records and reports required would be used not only for compliance monitoring, but also for compliance determinations. EPA does not intend to limit the use of other evidence admissible under the Federal Rules of Evidence. The Federal Rules of Evidence permit the introduction of all relevant evidence, subject to limited exceptions.

EPA is deferring decision on whether to make public any or all of the above reporting information required under § 82.13. EPA solicited public comment on this issue in its May 24, 1988 supplemental proposal. The reporting requirements will not become operative until after the rule takes effect, which will not occur before January 1, 1989, and the first reports will be submitted after that time. Affected persons must at the time of submission specify what of the submitted data is covered by 40 CFR Part 2, Subpart B, which governs the treatment of business information, or a waiver of any confidentiality claim will have occurred. EPA plans to make a determination as to the releasability of the reporting information at some future date.

13. Payment of Fees (§ 82.14)

In the preamble to the December 14 proposal, EPA discussed requiring payment of an administrative fee to cover the costs of operating the program (52 FR at 47505). This fee would be imposed under the Independent Offices Appropriation Act (31 U.S.C. 9701). The preamble described what activities might be covered by the fee, how EPA might determine the costs of these activities, and how the fee might be implemented. While seeking comment on these issues, EPA did not propose specific fee language in its proposed rule (proposed Section 82.14 was simply reserved for this purpose).

Many commenters objected to the imposition of an administrative fee. Fourteen chemical producers and users stated that the fee proposal had not been adequately detailed in the proposal, and that therefore EPA should not take final action without additional comment. Two chemical producers argued that EPA, by streamlining its administrative processes, could avoid any need for a fee to cover administrative costs.

EPA believes that modifications in the reporting and recordkeeping provisions have substantially reduced the administrative burden associated with the operations of the allocated quota system. Moreover, until the program begins, it is difficult to determine the costs of operation. The number of transfers and exports are unknown and will largely determine total program costs. Assuming a limited number of such transactions, EPA does not believe that substantial Agency resources will be required to operate the program and is concerned that the costs of operating the fee program will be a substantial share of the total costs of the allocated quota program.

Because of these concerns, EPA has not included in this notice a final provision requiring payment of an administrative fee. However, the Agency intends to reserve § 82.14 and will determine at some future date if resource costs justify promulgating an administrative fee requirement.

14. Appendices to Part 82

As part of the December 14 NPRM, EPA set forth several appendices to the proposed rule. Appendix A contains the ozone depletion weights for each of the controlled substances. These weights are based on the atmospheric lifetimes and the amount of bromine and chlorine in each of the chemicals contained on the list. The weights are used in determining the "calculated levels" of each controlled substance—the quantity of the chemical multiplied by its ozone depletion weight.

Appendix A contains the ozone depletion weights specified by the Montreal Protocol with one exception. EPA has included a weight of 6 for Halon 2402, whereas the Protocol leaves this weight for future determination.

EPA received several comments, questioning the scientific basis for the ozone depletion weights assigned to the halons. EPA clearly stated in the preamble to the December 14 NPRM that the weights assigned to the halons are based on more limited research than those assigned to the CFCs and therefore are substantially less certain. However, the current weights, including that assigned to Halon 2402, represent the best available information from the scientific community. Additional work is underway to review the determination of ozone depletion weights for each of the controlled substances. This analysis will be examined as part of the periodic assessments required by the Protocol and modifications to the weights will be made, if warranted. Moreover, if the Parties adopt a different weight for Halon 2402 than that contained in the final rule, the Agency will consider revising that aspect of the rule.

Two commenters from the refrigeration industry expressed concern that the weights for several of the CFCs

had changed from prior EPA publications and that the change had led to CFC-115 being "unexpectedly" added to the list of substances covered by the Montreal Protocol. EPA notes that the basis of the ozone depletion weights for the CFCs has not changed, but that the context in which the weights are being used has shifted. Early EPA studies reported weights on a per molecule basis which is generally more useful for the purposes of atmospheric modelling. When the context in which these weights were used shifted to regulatory controls, it becomes more appropriate to report weights on a per kilogram basis. Thus, the weight only changed to correspond to a change in the applicable unit of measurement. CFC-115 was appropriately included in the Protocol because it is among the commercially available fully halogenated compounds.

Taking these comments into consideration, EPA has not altered the ozone depletion weights included in Appendix A, but will continue to monitor relevant research and will modify these weights in the future if new information warrants such change.

15. Preemption of State and Local Regulations

Numerous commenters have urged EPA to state that the final rule preempts any state or local law. Section 159(b) of the Clean Air Act provides that if EPA adopts a regulation to protect the stratosphere, "no state or political subdivision thereof may adopt or attempt to enforce any requirement respecting the control of any such substance, practice, process, or activity to prevent or abate such a risk, unless the requirement of the state or political subdivision is identical to the subject of such regulation." EPA does not interpret section 159(b) as meaning that the adoption of any federal regulation of any substance, practice, process, or activity would preempt the entire field of stratospheric ozone regulation. As the Report by the Committee on Interstate and Foreign Commerce (House Report 95-294 (1977) p. 99) explained, "Thus, for example, if the Administrator were to promulgate regulations limiting or prohibiting use of halocarbon compounds as foaming or blowing agents in certain industrial processes, states and localities would be preempted from regulating or prohibiting such use of such compounds, except in accordance with federal regulation. State or local regulation of other uses of such compounds would not be preempted thereby, however." In EPA's view, states and political subdivisions would be prohibited from adopting any production or import limits not identical to those in EPA's regulation. However, since EPA's regulation only covers the production and importation of CFCs and halons, state or locally imposed limits, for example, on specific uses would not be precluded by the preemption provision.

V. Impact of Proposed Action

As part of its evaluation and response to public comments, EPA has revised its RIA. The results of the final RIA are described in the following sections. Significant comments received on the December RIA and on issues raised in the December 14 NPRM, along with EPA's response to these comments, are also presented.

A. Reductions in Ozone Depletion

Today's final action should substantially reduce the threat of stratospheric ozone depletion and the accompanying risks to human health and the environment. As shown earlier in Table 3, in the absence of regulatory action to limit the growth of CFCs and halons, ozone depletion of greater than 50 percent by the year 2075 would be likely. Implementation of the Protocol by the United States, most of the other developed nations and a large majority of the developing nations are projected to reduce the risks of depletion to under 2 percent in 2075. Because 37 nations have already signed the Montreal Protocol, assumptions concerning widespread participation by both developed and developing countries appear reasonable.

Given the large uncertainties inherent in the current atmospheric models, in projecting long-term growth rates for the relevant trace gases, and in predicting the degree of participation by other nations in the Protocol, EPA believes its action represents a reasonable response to the ozone depletion threat established by the scientific evidence available at the time of this rulemaking. However, as described above, the Ozone Trends Panel Summary suggests that important new evidence will soon be available. EPA intends to seek public comment on the full report when it becomes available and integrate this new evidence into a supplemental risk assessment the Agency is currently preparing. EPA also intends to work toward expediting and actively participating in upcoming assessments and reviews called for by the Montreal Protocol.

B. Economic Impact

As part of the accompanying RIA, EPA examined the potential costs to United States industry of meeting various levels of reductions in CFC and halon production and consumption. It also analyzed and compared these costs to the potential health and environmental benefits of reduced exposure to harmful ultraviolet radiation which would result from measures to protect the ozone layer. The health and environmental benefits assessed are those accruing to the United States alone, but are based on the assumption that most other nations, through their participation in the Montreal Protocol, join in making the same level of reductions undertaken by this country.

As explained in the preamble to the December 14 NPRM and detailed in the final RIA, the cost analysis takes a "bottom up" approach. It examines uses of CFCS and halons within eight major industrial groupings: Refrigeration; air conditioning; flexible foam; rigid foam; solvent cleaning; sterilization; fire extinguishant; and miscellaneous. Within these larger groupings it examined 74 specific use applications (e.g., commercial refrigeration, home refrigeration, etc.). To determine costs, the RIA examined over 900 technologically feasible options for reducing consumption of these chemicals. Since many of these options were eliminated from consideration because of high costs or possible toxicity, the analysis drew from approximately 300 technically feasible responses to controlling the use of CFCs and halons.

The potential benefits examined in the RIA also cover a broad range of health and environmental impacts. Any significant shift in the quantity and make-up of ultraviolet radiation striking the earth's surface would represent a major change in one of the basic environmental parameters, affecting most forms of biological life. While the RIA attempts to quantify some of the likely major impacts (e.g., skin cancers), limited research completed to date prevents the quantification of other potentially significant risks (e.g., immune suppression).

1. Economic Costs of Reductions

The analysis contained in the RIA examines and provides cost estimates for a wide variety of different control options over a long period of time. The types of controls examined include: Engineering controls; chemical substitutes; product substitutes; changes in work practices; and recycling and recovery technologies. The analysis sought to include technologies that were currently available, along with those that were likely to become commercially available over the next decade. It also took into consideration such factors as

changes in energy costs and compliance with other relevant environmental requirements (e.g., water pollution or worker exposure restrictions).

Estimates of the costs of reducing CFC or halon use to specified levels are developed using the Integrated Assessment Model (IAM), which is detailed in Appendix I of the RIA. Essentially, this model operates by prioritizing the potential reductions in CFC and halon use on the basis of least cost and the judgment of EPA contractors and staff based on discussions with industry representatives on how firms are likely to respond to reduction requirements. Several commenters raised concerns with the RIA's cost projections. Two chemical producers stated that EPA had underestimated the costs of reductions. In particular, they claimed that the large number of options that EPA predicted would save money suggested that EPA had left out factors affecting costs. EPA has reviewed its cost documentation and analysis and modified some of the cost estimates based on the additional information provided by commenters. (Specific changes are presented in Part 10 of Volume III of the RIA.) However, EPA's information and analysis still show that many options to reduce CFC and halon use can be implemented at little or no cost, and in some cases can decrease costs. Cost-saving options exist because all firms involved in using CFCs and halons do not possess perfect information as to available controls. Recent attention to this issue has already dramatically reduced the cost of obtaining information on control options. As a result, firms in certain industry segments are beginning to shift away fron these chemicals without incurring production cost increases. In any event, the RIA assumed zero costs (i.e., no cost savings) for those controls which EPA believes in some cases, based on engineering analysis, can save firms money.

Other commenters stated that an industry-supported economic analysis (Putnam, Hayes and Bartlett, 1987), which they argued contained cost projections that were substantially greater than those of the preliminary RIA, presented a more realistic estimate of future costs of compliance. EPA has reviewed both the methodology and the results of the industry's study. Unlike EPA's RIA which linked costs and reductions to specific technologies, the industry's analysis is based on industry's expert opinion on the quantity of reductions it would make if CFC prices increased by a certain amount. Because of this streamlined approach to estimating costs, it is extremely difficult to identify and compare specific differences in the two studies. Nonetheless, the results of the two studies do not differ dramatically. In fact, when differences in scope (e.g., treatment of halons) are taken into account, the industry's analysis generally falls well within the range of estimates presented in the RIA accompanying both the proposed and final rules.

In addition to making corrections and including new information provided in the public comments, EPA has also updated the engineering costs contained in its RIA to reflect rapidly emerging technologies to reduce and replace CFCs and halons. For example, in the time since the December NPRM was published, the food packaging industry reached an agreement to voluntarily eliminate its use of CFC-11 and -12 (generally by shifting to HCFC-22 and blends) by the end of this year. A major chemical producer has announced a blend of CFC-113 which contains 25-30 percent less of this chemical than current formulations at no additional costs and with no loss in cleaning effectiveness. A large electronics firm working with a small chemical company announced a terpene-based solvent substitute for use in some electronics cleaning. Work has also progressed on alternative blowing agents (e.g., HCFC-22, HCFC-141b, and HCFC-123) for many foam applications including insulation. Segments of the car air conditioning and servicing industries and the air conditioning and refrigeration industries have stepped up activities aimed at facilitating increased recycling and recovery at the time of servicing. In addition, further testing has been conducted on a blend containing dimethylether which reduces the use of CFC-12 in existing refrigeration and auto and space air conditioners. These options have now been incorporated into the RIA's cost analysis. Some are already being used by firms and are therefore considered in each scenario examined. Others, though promising, are not yet fully proven and commercially available, and therefore are examined as part of different cases (scenarios) presented in the RIA which compare the costs of compliance based on different assumptions about the timing and market penetration of various control technologies.

To reflect the substantial impact that the timing and degree to which these technologies are adopted by user industries have on cost estimate projections, the analysis in the RIA focuses on two cases. The differences in these cases are the rate at which firms adopt these measures, the percent of the firms in an industry who take this action (e.g. market penetration), and the quantity of emission reductions achieved by the technology. Case 1 assumes that key user industries delay their adoption of reduction technologies, market penetration of these controls is limited, and the magnitude of reductions they achieve is on the low end of the amount that now seems plausible. In contrast, Case 2 assumes that technologically available low-cost reductions are adopted expeditiously by key user industries. Specifically, in Case 2, the RIA assumes the following reduction technologies are employed within the next few years: Shifts to HCFC-22 in specific markets for rigid foam insulation; increases in recovery of CFCs from refrigeration; switches by some percentage of hospitals to disposable instruments and steam cleaning instead of CFC based sterilization; improved housecleaning by solvents users and substantial shifts to CFC-113 blends, terpene or aqueous cleaners; increases in recycling of CFC-12 at large auto shops when servicing car air conditioners; and shifts to water blown foam or modified polyols by molded and slabstock flexible foamers.

Table 4 presents the total social costs of complying with Case 1 and 2 for reductions required by the final rule (i.e., the Montreal Protocol case). It demonstrates that the costs through 2000 of meeting the control requirements could nearly triple depending on the rate at which firms adopt reduction technologies. The cost differential is substantially greater for the near term rather than over the longer term.

Table 4 also shows the potential windfalls or transfer payments which would result from this regulation. The potential amount of windfalls also varies considerably between the Case 1 and 2, particularly in the early years. The analysis suggests that even in Case 2, with its optimistic assumptions about shifts away from CFCs, the allocated quota system would create windfalls of almost $2 billion dollars through the turn of the century.

TABLE 4.—SOCIAL AND TRANSFER COST ESTIMATES FOR CASES 1 AND 2 COST SCENARIOS [a]

[In millions of 1985 dollars]

	Case 1	Case 2
Social Costs: [b]		
1989-2000	2,730	1,012
1989-2075	39,530	20,760

TABLE 4.—SOCIAL AND TRANSFER COST ESTIMATES FOR CASES 1 AND 2 COST SCENARIOS [a]—Continued

[In millions of 1985 dollars]

	Case 1	Case 2
Transfer Costs: [c]		
1989-2000	7,300	1,900
1989-2075	13,600	6,900

[a] The assumed stringency and coverage used in this analysis are those of the CFC 50%/Halon Freeze case described in Chapter 5 of the RIA. CFCs are regulated with an initial freeze in 1989 at 1986 levels, 20 percent reduction in 1993, and 50 percent reduction in 1998, and halons are frozen at 1986 levels in 1992. The assumed rate of growth in CFC and halon use is the Middle Growth Scenario described in Chapter 4 of the RIA.

[b] Social costs are discounted at 2 percent.

[c] Transfer costs are discounted at a rate of 6 percent to reflect the opportunity cost of funds in the private sector. Transfer costs are not reduced by the taxes that would be paid on them.

Table 5 shows the CFC price increase for the final rule that would result from the assumptions about cost controls contained in the Cases 1 and 2. The increase in CFC prices will also vary dramatically based on the rate at which CFC user industries employ reduction technologies.

TABLE 5.—PROJECTED CFC AND HALON PRICE INCREASES FOR THE CASES 1 AND 2 COST SCENARIOS [a]

[1985 dollars]

	Control cost scenarios	
	Case 1	Case 2
CFC Price Increases:		
1989	6.69	0.00
1991	1.84	0.00
1993	3.93	1.55
1995	3.77	1.59
2000	5.48	3.77

[a] The stringency and coverage assumptions used are those of CFC 50%/Halon Freeze case described in Chapter 5 of the RIA. CFCs are regulated with an initial freeze in 1989 at 1986 levels, 20 percent reduction in 1993 and 50 percent reduction in 1998, and halons froze at 1986 levels in 1992. The assumed growth in CFC and halon use is the Middle Growth Case described in Chapter 4. Price increases are cited on a standardized "ozone-depleting equivalent" basis per kilogram.

2. Health and Environmental Benefits

The preliminary RIA described a wide range of potential health and environmental effects of ozone depletion. This description was based largely on the analysis contained in EPA's risk assessment.

As described in the risk assessment (and the SAB's review of it), varying amounts of research have been completed on different health and environmental effects. For example, while considerable research has led to the identification of a dose-response relationship between UV-B radiation and nonmelanoma skin cancer, only a limited number of case studies exist showing the nature of the impact of increased UV-B radiation on the formation of groundlevel ozone (smog). In fact, the SAB panel's interim report stated that they believed that the potential risk of harm was greater for some of the health and environmental effects where little was known (e.g., immune suppression and damage to plants and aquatics organisms) than for other areas where better information was available (e.g., skin cancers).

Because of these concerns, EPA attempted to develop dose-response relationships for many of the potential health and environmental impacts. This sometimes involved extrapolating from short-term case studies on one or more species or regions. EPA quantified these effects primarily to provide policy-makers with an illustration of the potential magnitude of impacts in these areas. Substantially more research will be necessary before reliable dose-response estimates are possible, particularly in the areas of plant and aquatic effects.

A chemical company and an industry research organization criticized EPA's efforts to quantify one or more of the potential environmental impacts (e.g., plant and aquatic effects, urban ozone formation and polymer degradation). As discussed above, EPA recognizes the limitations inherent in extrapolations from limited case studies, but believes that the analysis contains the appropriate caveats and, on balance, provides useful information for policy-makers. A public interest group criticized EPA for not including experimental results from Antarctica demonstrating dramatic losses in phytoplankton from increased exposure to UV-B radiation. EPA did not include this information in the RIA analysis because it has not yet been peer reviewed and therefore is of a preliminary nature. The Agency intends to more fully explore the potential health and environmental effects of the Antarctica ozone hole as part of its update of its risk assessment.

One chemical producer and a government agency criticized the RIA's estimates of future skin cancer cases and deaths. They suggested that the public would modify its behavior and avoid exposure and/or that improvements in medical technology would reduce damage and deaths from this form of cancer.

EPA knows of no evidence supporting the theory that behavior will be modified to avoid exposure. It also notes that behavioral changes, if they occurred, would themselves be a cost of ozone depletion. Nonetheless, the RIA includes a sensitivity analysis which reduces by 25 percent predicted mortality rates for skin cancers. In another sensitivity analysis, all mortality rates are reduced (e.g., medical advances decrease mortality from all causes not just from skin cancers). These results are presented in Chapter 10 of the final RIA and show the reduced number of projected deaths from skin cancers which occur under these assumptions.

One commenter raised the question of whether a recent report showing that UV-B radiation had decreased in the past decade suggested that the models linking ozone depletion to increased UV-B radiation were inaccurate. Accepted scientific theory suggests, if the ozone layer had depleted over the past decade, UV-B radiation striking the earth should have increased. EPA has reviewed the study cited by the commenter and believes that several aspects of its design may make its results unreliable. While the physical properties of ozone's absorption of UV-B radiation are well established in the scientific community, this particular study is based on a limited network of monitoring stations. Moreover, the monitoring sites are typically located near airports where increases in local pollution could have influenced the results. Nor has the effect of possible changes in local weather conditions (e.g., cloud cover and precipitation) been evaluated. EPA will continue to monitor research related to direct measurements of UV-B radiation, but does not believe that the study mentioned by the commenter provides sufficient grounds for altering its current assessment.

Other commenters stated that the relationship between UV-B and both melanoma and cataracts was so uncertain that it could not be quantified. While EPA recognizes that greater uncertainty exists as to the dose response relationship for these health effects, the RIA applies the methodology developed and reviewed as part of EPA's risk assessment document. In the case of melanoma, EPA conducted an extensive review of the literature and organized a panel of experts to explore its relationship to UV-B radiation. For both melanoma and cataracts, the findings contained in the EPA's risk assessment were extensively reviewed and approved by the SAB.

Table 6 provides a summary of the health and environmental benefits of reducing ozone depletion to the extent that would occur if the Montreal

Protocol were widely implemented. Because of the uncertainties in these estimates, it also provides a range of values based on sensitivity analyses of key variables.

TABLE 6.—SUMMARY OF BENEFITS FROM REDUCED OZONE DEPLETION [a]

	Reference scenario
Skin cancer cases (low and high sensitivity).	173.9 million (91 million to 306 million).
Skin cancer deaths (low and high sensitivity).	3.7 million (1.9 million to 6.8 million).
Cataract cases (low and high sensitivity).	19.1 million (10.4 million to 26.0 million).
Damage to crop yields (low and high sensitivity).	7 percent (extrapolation of soybean dose-response).
Decrease in fish harvests (low and high sensitivity).	25 percent (extrapolation of anchovy dose-response).
Damage to polymers (low and high sensitivity).	3.6 billion (extrapolation of PVC dose-response).
Increase in tropospheric ozone (low and high sensitivity).	29 percent (based on case studies from three cities).
Sea level rise (low and high sensitivity).	12.6 cm (± 50 percent).
Non-quantified Benefits	
Increase in actinic keratosis Immune suppression	
Tropospheric ozone impacts on pulmonary system.	
Pain and suffering from skin cancer.	
All temperature related effects.	
Beach erosion from sea level rise.	
Loss of coastal wetlands from sea level rise.	
UV effects on aquatic and terrestrial ecosystems.	
Tropospheric ozone impacts on non-grain crops, forests, other plant species, and man-made materials.	
UV effects on materials currently in use.	

[a] Benefits are derived by comparing health and environmental impacts in the absence of control (i.e. no controls case) to the Montreal Protocol case (i.e. 50% CFC/halon freeze case).

Assumptions

1. Benefits. Benefit estimates are estimated for the United States only.

2. Time horizon. Table shows avoided damages from Montreal Protocol case relative to "no controls" for populations alive today and born before 2075.

3. Dose-response. Health effects (skin cancer cases and deaths and cataract cases) are modelled based on dose-response estimates developed for EPA's risk assessment (EPA, 1987), and are summarized in Chapter 7 of EPA's Regulatory Impact Analysis (EPA, 1988). Damage to crops from UV-B is presented for grain crops only based on dose-response developed for soybeans (EPA, 1987 and 1988). Damage to fish; is estimated for commercial harvest of fin and shell fish based on dose-response models developed for anchovies (EPA, 1987 and 1988). Increase in tropospheric ozone and damage to crops are based on case studies of 3 U.S. cities and national crop loss model (EPA, 1987 and 1988). Polymer estimates are based on dose-response models developed for PVC and extended to include acrylics and polyesters (EPA, 1987 and 1988). Sea level rise estimates based on parameterized radiative-corrective model modified to compute thermal expansion, (EPA, 1987 and 1988).

4. Sensitivity. Range for health effect estimates based on high and low dose-response coefficients.

3. Comparison of Costs and Benefits

Based on the costs and benefits presented above and detailed in the RIA, today's final action should result in a substantial net gain to society.

Comments on the RIA accompanying the December NPRM raised several issues concerning assumptions used in valuing benefits. Two federal agencies questioned the statistical value of life used in the RIA. One argued that it was too low and the other that it was too high. The preliminary RIA used a range of from $2–5 million with a reference case value of $3 million. Following a review of the economic literature, the final RIA maintains the value of $3 million, but a new study (Viscusi, 1988) suggests that this figure may substantially underestimate risks. As a result, a sensitivity analysis using a $12 million dollar value of life is also presented. A value of $2 million has been retained in the RIA to represent the low end of the range. These figures are used for illustrative purposes in performing the analysis in the RIA. Based on its review of the comments, the RIA does not conclude whether the value of reducing risks to human life for involuntary risks can be limited to $3 million dollars or whether it should be higher as suggested by new information contained in the economic's literature (Visusi, 1988).

A government agency also stated that the discount rate used in assessing costs and benefits over time was too low and that the RIA inappropriately increased the future value of life. Another government agency stated that the value of human lives should not be discounted. Appendix G of the RIA presents the justification for the assumptions contained in the final RIA. Where the benefits are long-lived and long lags exist before the benefits accrue, a discount rate toward the lower end of the range commonly understood as representative of the social rate of time preference was selected as an appropriate illustration in conducting the RIA.

The RIA increases the value of life over time to reflect the assumption that as society becomes wealthier, people are willing to pay greater amounts of money to reduce risks. EPA believes that this assumption is true and necessitates increasing the future value of life in the analysis. The RIA contains sensitivity analyses which examine alternative assumptions for both of these factors. These results do not alter the conclusion of the analysis.

VI. Additional Information

A. Executive Order 12291

Executive Order (E.O.) 12291 requires the preparation of a regulatory impact analysis for major rules, defined by the order as those likely to result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic industries; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

EPA has determined that this rule meets the definition of a major rule under E.O. 12291, and has prepared a regulatory impact analysis (RIA). Drafts of that document and this notice of rulemaking were submitted to the Office of Management and Budget (OMB) for review under Executive Order 12291. Any comments from OMB and any EPA responses to such comments are available for public inspection at the Central Docket Section, South Conference Room 4, Docket No. A-87-20, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. A copy of the RIA has also been placed in the rulemaking docket.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, requires that Federal agencies examine the impacts of their regulations on small entities. Under 5 U.S.C. 604(a), whenever an agency is required to publish a general notice of proposed rulemaking, it must prepare and make available for public comment an initial regulatory flexibility analysis (RFA). Such an analysis is not required

if the head of an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, pursuant to 5 U.S.C. 605(b). EPA prepared an initial regulatory flexibility analysis when the regulation was proposed on December 14, 1987. This initial RFA draft was placed in the public docket for public comment.

The final draft of the RFA has incorporated comments submitted during the public comment period in response to the proposed rule. These comments refined EPA's cost estimates of alternative substitutes available, both product and chemical, to all industries affected by the regulation. The final RFA concludes that of the many industries affected by regulations of CFCs and halons that only some segments of the foam-blowing industry were potentially at risk. In contrast to almost all other uses of these chemicals, it is only in the foam industry that CFCs are a large percentage of final product cost. Significant price increases of CFCs could potentially affect the current market share of these products.

Different segments of the foam industry are likely to be affected in different ways. Some segments have currently available technologies which are cost competitive with potential product substitutes. For example, as discussed above, the foam food packaging industry has entered into a voluntary agreement to shift out of CFC-11 and -12 blown foam to use HCFC-22 and blends by the end of the year. Thus, the impact on this industry segment will be minimal. Similarly, the industry segment that makes flexible molded foam (used primarily for seat backs of autos) is capable of eliminating the use of CFC-11 as an auxiliary blowing agent with minimal cost impact. A major supplier to the extruded polystyrene boardstock insulation industry also recently announced plans to eliminate the use of CFC-12 in the manufacture of these products consistent with the availability of substitutes. Together, these shifts represent a significant share of total use of CFCs by the foam industry.

However, the situation is less clear for two segments—polyurethane sprayed and foam insulation and boardstock. The insulating board foam industry is experimenting with several alternative blowing agents (HCFC-22, HCFC-123 and HCHC-141b). To the extent these substitutes are determined to be technically and economically viable, the longer term impact on these firms will be minimized. However, the near term impact (before substitutes are commercially available) will be largely determined by the cost of CFCs, which, in turn, rests on the speed at which other industries reduce their demand for these chemicals and the product quality and consumer preference for product substitutes. The RFA estimates that the market for these two foams will not grow as much in the future, and may shrink under pessimistic assumptions about market penetration of product substitutes. However, the expected impact for current market share of these foams manufacturers are minimal.

The foam industry comments on the RFA asserted that EPA's description of the structure of the industry was overly simplistic and its portrayal of the control options available in part inaccurate. The information provided by the commenters has led EPA to modify both of these aspects for the analysis. The revised analysis includes a more detailed breakdown of the industry and revised and updated engineering costs for reduction technologies (e.g., HCFC-22 for food packaging and polyethylene, HCFC-141b as a possibility for polyurethane, etc.). EPA has attempted further to refine energy costs related to product substitutes for insulation and to better understand consumer demand for high quality or established goods when inexpensive product substitutes are available as in the case of rigid foam packaging which will likely maintain their market share despite the availability of low-cost substitutes.

Based on the analysis contained in the revised RFA, EPA does not believe that any foam industry segment will be substantially harmed over the long term. It recognizes, however, that short-term CFC price jumps, if they occur, would have a significant impact on the competitiveness on the rigid foam insulation market. To address this concern, EPA intends to closely monitor the price of CFCs and the progress made by all industries in reducing their use of these chemicals.

C. Paperwork Reduction Act

As required by § 35.04(H) of the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.*, EPA has submitted a copy of these revised information collection requirements to the Office of Management and Budget for its review.

OMB has tentatively approved the paperwork sections other than § 82.12. EPA has reserved § 82.12 and is still reviewing alternative approaches to implement a trading program. OMB expects to complete the approval process of paperwork requirements other than those necessary to implement § 82.12 and will assign an information collection control number after the 30 day comment period.

Public reporting burden for this collection of information is estimated to average 52 hours per response for producers, 48 hours per response for importers, and 4 hours per response for exporters. These estimates include time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. All recordkeeping requirements are considered to be "usual and customary" burden as defined under 5 CFR 1320.7 and, as such, are not included in the estimate of respondent burden.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

VII. References

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List of Subjects in 40 CFR Part 82

Administrative practice and procedure, Intergovernmental relations, Exports, Imports, Stratospheric ozone, Reporting and recordkeeping requirements.

Date: August 1, 1988.

Lee M. Thomas,

Administrator.

For the reasons set forth in the preamble, Title 40 CFR Part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for Part 82 continues to read as follows:

Authority: 42 U.S.C. 7157(b).

2. Part 82 is amended by adding §§ 82.1–82.14 and Appendices A through D to read as follows:

Sec.
82.1 Purpose and scope.
82.2 Effective date.
82.3 Definitions.
82.4 Prohibitions.
82.5 Apportionment of baseline production allowances.
82.6 Apportionment of baseline consumption allowances.
82.7 Grant and phased reduction of baseline production and consumption allowances for Group I Controlled Substances.
82.8 Grant and freeze of baseline production and consumption allowances for Group II Controlled Substances.
82.9 Availability of production allowances in addition to baseline production allowances.
82.10 Availability of consumption allowances in addition to baseline consumption allowances.
82.11 Exports to parties.
82.12 Transfers of production and consumption allowances [Reserved].
82.13 Recordkeeping and reporting requirements.
82.14 Payment of fees [Reserved].
* * * * *
Appendix A—Controlled substances and ozone depletion weights.
Appendix B—Parties to the Montreal Protocol [Reserved].
Appendix C—Nations complying with, but not party to, the protocol [Reserved].
Appendix D—Twenty-five-kilotonne parties [Reserved].

§ 82.1 Purpose and scope.

(a) The purpose of these regulations is to implement the *Montreal Protocol on Substances that Deplete the Ozone Layer* under authority provided by section 157 of the Clean Air Act. The Montreal Protocol requires each nation that becomes a Party to the Protocol to limit its total production and consumption (defined as production plus imports minus exports) of certain ozone-depleting substances according to a specified schedule. The Protocol also requires Parties to impose certain restrictions on trade in ozone-depleting substances with nonparties.

(b) This rule applies to any individual, corporate, or governmental entity that produces, imports, or exports controlled substances.

§ 82.2 Effective date.

Section 82.13(f)(1) of this part takes effect September 12, 1988. The remainder of the regulations under this part will take effect when the Montreal Protocol enters into force. The Montreal Protocol will enter into force on January 1, 1989, provided that at least 11 instruments of ratification, acceptance, approval of the Protocol or accession thereto have been deposited by States or regional economic integration organizations representing at least two-thirds of 1986 estimated global consumption of the controlled substances. If these conditions have not been fulfilled by January 1, 1989, the Protocol will enter into force on the ninetieth day following the date on which the conditions have been fulfilled.

§ 82.3 Definitions.

As used in this part, the term:

(a) "Administrator" means the Administrator of the Environmental Protection Agency or his authorized representative.

(b) "Baseline consumption allowances" means the consumption allowances apportioned under § 82.6.

(c) "Baseline production allowances" means the production allowances apportioned under § 82.5.

(d) "Calculated level" means the level of production, exports or imports of controlled substances determined for each Group of controlled substances by:

(1) Multiplying the amount (in kilograms) of production, exports or imports of each controlled substance by that substance's ozone depletion weight listed in Appendix A to this Part; and

(2) Adding together the resulting products for the controlled substances within each Group.

(e) "Consumption allowances" means the privileges granted by this Part to produce and import calculated levels of controlled substances; however, consumption allowances may be used to produce controlled substances only in conjunction with production allowances. A person's consumption allowances are the total of the allowances he obtains under § 82.7 (baseline allowances for Group I controlled substances), § 82.8 (baseline allowances for Group II controlled substances), and § 82.10 (additional consumption allowances upon proof of exports of controlled substances), as may be modified under § 82.12 [1] (transfer of allowances).

(f) "Control periods" means those periods during which the prohibitions under § 82.4 apply. Those periods are:

(1) For Group I controlled substances: [reserved]

(2) For Group II controlled substances: [reserved]

(g) "Controlled substance" means any substance listed in Appendix A to this Part, whether existing alone or in a mixture, but excluding any such substance or mixture that is in a manufactured product other than a container used for the transportation or storage of the substance or mixture. Any amount of a listed substance which is not part of a use system containing the substance is a controlled substance. If a listed substance or mixture must first be transferred from a bulk container to another container, vessel, or piece of equipment in order to realize its intended use, the listed substance or mixture is a controlled substance. Controlled substances are divided into two groups, Group I and Group II, as set forth in Appendix A.

(h) "Export" means the transport of controlled substances manufactured from raw materials or feedstock chemicals (i.e., virgin production) from within the United States or its territories to persons or countries outside the United States or its territories, excluding United States Military bases and ships for on-board use.

(i) Exporter means the person who contracts to sell controlled substances for export, or transfers controlled substances to his affiliate in another country.

(j) "Facility" means any process equipment (e.g., reactor, distillation column) to convert raw materials or feedstock chemicals into controlled substances.

(k) "Import" means the transport of virgin, used and recycled controlled substances from outside the United States or its territories to persons within the United States or its territories.

(l) "Importer" means the importer of record listed on U.S. Customs Service Form 7501 for imported controlled substances.

(m) "Montreal Protocol" means the *Montreal Protocol on Substances that Deplete the Ozone Layer* which was adopted on September 16, 1987, in Montreal, Canada.

(n) "Nations complying with, but not joining, the Protocol" means any nation listed in Appendix C to this Part.

(o) "Party" means any nation that is a party to the Montreal Protocol and listed in Appendix B to this part.

(p) "Person" means any individual or legal entity, including an individual,

[1] **Editorial Note:** Section 82.12 is currently reserved. The Environmental Protection Agency will add regulations in that section at a future date.

corporation, partnership, association, state, municipality, political subdivision of a state, Indian tribe, and any agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.

(q) "Plant" means one or more facilities at the same location owned by or under common control of the same person.

(r) "Potential production allowances" means the production allowances obtained under § 82.9 (a) and (b).

(s) "Production" means the manufacture of a controlled substance from any raw material or feedstock chemical (i.e., virgin production); however, production does not include the manufacture by one person of controlled substances that are used and entirely consumed in the manufacture by the same person of other chemicals.

(t) "Production allowances" means the privileges granted by this Part to produce calculated levels of controlled substances; however, production allowances may be used to produce controlled substances only in conjunction with consumption allowances. A person's production allowances are the total of the allowances he obtains under § 82.7 (baseline allowances for Group I controlled substances), § 82.8 (baseline allowances for Group II controlled substances), and § 82.9 (c) and (d) (additional production allowances), as may be modified under § 82.12 [1] (transfer of allowances).

(u) "Twenty-five-kilotonne Party" means any nation listed in Appendix D to this Part.

(v) "Unexpended consumption allowances" means consumption allowances that have not been used. At any time in any control period, a person's unexpended consumption allowances are the total of the calculated level of consumption allowances he has authorization under this Part to hold at that time for that control period, minus the calculated level of controlled substances that the person has produced and imported in that control period until that time.

(w) "Unexpended production allowances" means production allowances that have not been used. At any time in any control period, a person's unexpended production allowances are the total of the calculated level of production allowances he has authorization under this Part to hold at that time for that control period, minus the calculated level of controlled substances that the person has produced in that control period until that time.

[1] Editorial note: Section 82.12 is currently reserved. The Environmental Protection Agency will add regulations in that section at a future date.

§ 82.4 Prohibitions.

(a) No person may produce, at any time in any control period, a calculated level of controlled substances in excess of the amount of unexpended production allowances held by that person under the authority of this Part at that time for that control period. Every kilogram of such excess constitutes a separate violation of this regulation.

(b) No person may produce or import, at any time in any control period, a calculated level of controlled substances in excess of the amount of unexpended consumption allowances held by that person under the authority of this Part at that time for that control period. Every kilogram of such excess constitutes a separate violation of this regulation.

(c) A person may not use his production allowances to produce a quantity of controlled substances unless he holds under the authority of this Part at the same time consumption allowances sufficient to cover that quantity of controlled substances, nor may he use his consumption allowances to produce a quantity of controlled substances unless he holds under authority of this Part at the same time production allowances sufficient to cover that quantity of controlled substances. However, consumption allowances alone are required to import controlled substances.

(d) Beginning one year after the effective date of this Part, no person may import any quantity of controlled substances from any nation not listed in Appendix B to this Part (Parties to the Montreal Protocol), unless that nation is listed in Appendix C to this part (Nations Complying with, But Not Party to, the Protocol). Every kilogram of controlled substances imported in contravention of this regulation constitutes a separate violation of this regulation.

§ 82.5 Apportionment of baseline production allowances.

Persons who produced one or more controlled substances in 1986 are apportioned calculated levels of baseline production allowances as set forth in paragraphs (a) and (b) of this section. Each person's apportionment is equivalent to the calculated levels of that person's production of Group I and Group II controlled substances in 1986.

(a) For Group I controlled substances:

Person	Calculated level
Racon, Inc	13,785,068
Kaiser Chemicals	28,187,273
Pennwalt Corp	39,126,239
Allied-Signal, Inc	77,701,820
E.I. du Pont de Nemours & Co., Inc	152,221,000

(b) For Group II controlled substances:

Person	Calculated level
E.I. du Pont de Nemours & Co., Inc	32,200,000
Great Lakes Chemical Corp	20,147,961
ICI Americas, Inc	6,406,452

§ 82.6 Apportionment of baseline consumption allowances.

Persons who produced, imported, or produced and imported one or more controlled substances in 1986 are apportioned calculated levels of baseline consumption allowances as set forth in paragraphs (a) and (b) of this section.

(a) For Group I controlled substances:

Person	Calculated level
Racon, Inc	13,466,026
Kaiser Chemicals	27,616,217
Pennwalt Corp	38,220,699
Allied-Signal, Inc	74,043,943
E.I. du Pont de Nemours & Co., Inc	139,373,484
Atochem, Inc	2,204,113
Pharmachem, Inc	28,602
Sumitomo Corporation of America	229,930
Hoechst Celanese Corp	329,597
Refricentro, Inc	420,931
Kali-Chemie Corp	437,940
National Refrigerants, Inc	3,069,091
ICI Americas, Inc	6,310,917
Holchem, Inc	212,159

(b) For Group II controlled substances:

Person	Calculated level
E.I. du Pont Nemours & Co., Inc	27,731,067
Great Lakes Chemical Corp	19,855,268
ICI Americas, Inc	6,347,800
Ausimont USA, Inc	206,400
Atochem, Inc	2,126,427
Kali-Chemie Corp	1,533,800

§ 82.7 Grant and phased reduction of baseline production and consumption allowances for Group I controlled substances.

(a) For each of the control periods that begins before July 1, 1993, every person is granted 100 percent of the baseline production and consumption allowances apportioned to him under §§ 82.5(a) and 82.6(a).

(b) For each of the control periods that occurs between July 1, 1993, and June 30, 1998, inclusive, every person is granted 80 percent of the baseline production and consumption allowances apportioned to him under §§ 82.5(a) and 82.6(a).

(c) For each of the control periods that begins after June 30, 1998, every person is granted 50 percent of the baseline production and consumption allowances apportioned to him under §§ 82.5(a) and 82.6(a).

§ 82.8 Grant and freeze of baseline production and consumption allowances for Group II controlled substances.

For each of the control periods specified in § 82.3(f)(2), every person is granted 100 percent of the baseline production and consumption allowances apportioned to him under §§ 82.5(b) and 82.6(b).

§ 82.9 Availability of production allowances in addition to baseline production allowances.

(a) Every person apportioned baseline production allowances for Group I controlled substances under § 82.5(a) is also granted a calculated level of potential production allowances equivalent to:

(1) 10 percent of his apportionment under § 82.5(a), for each control period ending before July 1, 1998; and

(2) 15 percent of his apportionment under § 82.5(a), for each control period beginning after June 30, 1998.

(b) Every person apportioned baseline production allowances for Group II controlled substances under § 82.5(b) is granted a calculated level of potential production allowances equivalent to 10 percent of his apportionment under § 82.5(b), for each control year specified in § 82.3(f)(2).

(c) A person may convert potential production allowances, either granted to him under paragraphs (a) and (b) of this section or obtained by him under § 82.12 [1] (transfer of allowances), to production allowances only to the extent authorized by the Administrator under § 82.11 (Exports to Parties). A person may obtain authorization to convert potential production allowances to production allowances either by requesting issuance of a notice under § 82.11 or by completing a transfer of authorization under § 82.12.[1]

(d) Any person may obtain production allowances from, or transfer his production allowances to, a foreign entity in accordance with the provisions of this paragraph.

(1) A nation listed in Appendix D to this part (Twenty-five-kilotonne Parties) must agree to either transfer to the person at a specified time some amount of the calculated level of production that the nation is permitted under the Montreal Protocol or receive from the person at a specified time some amount of the calculated level of production that the person is permitted under this part. The person must obtain from the principal diplomatic representative in that nation's embassy in the United States a document clearly stating that the nation agrees to reduce or increase, as applicable, its allowable calculated level of production by the amount being transferred to or from the recipient for the control period(s) to which the transfer applies and that after the transfer the nation's total allowable production of controlled substances will not exceed 25 kilotonnes.

(2) The person must submit to the Administrator a transfer request that includes a true copy of the document required by paragraph (d)(1) of this section and that sets forth the following:

(i) The identity and address of the person;

(ii) The identity of the Twenty-five-kilotonne Party;

(iii) The names and telephone numbers of Contact persons for the person and for the Twenty-five-kilotonne Party;

(iv) The amount of allowable calculated level of production being transferred;

(v) The control period(s) to which the transfer applies; and

(vi) For transfers to Twenty-five kilotonne Parties, the Twenty-five kilotonne Party's total allowable calculated level of production following the proposed transaction.

(3) After receiving a transfer request that meets the requirements of paragraph (d)(2) of this section, the Administrator will complete the following steps:

(i) Review any proposed transfer of production allowances to a Twenty-five-kilotonne Party and approve the transfer if it is consistent with the Montreal Protocol and domestic policy. The Administrator will consider the following factors in deciding whether to approve such a transfer:

(A) Possible creation of economic hardship;

(B) Possible effects on trade; and

(C) Potential environmental implications.

(ii) Notify the Secretariat of the Montreal Protocol of the transfer to the person or to the Twenty-five-kilotonne Party if approved under paragraph, (d)(3)(i) of this; and

(iii) Issue the person a notice granting or deducting production allowances equivalent to the calculated level of production transferred, and specifying the control periods to which the transfer applies. The change in production allowances will be effective on the date that the notice is issued.

§ 82.10 Availability of consumption allowances in addition to baseline consumption allowances.

(a) Except as limited by paragraph (b) of this section, any person may obtain, in accordance with the provisions of this subsection, consumption allowances equivalent to the calculated level of controlled substances (other than recycled or used controlled substances) that the person has exported from the United States or its territories. The consumption allowances granted under this section will be valid only during the control period in which the exports departed the United States or its territories.

(1) The exporters of the controlled substances must submit to the Administrator a request for consumption allowances setting forth the following:

(i) The identities and addresses of the exporter and the recipient of the exports;

(ii) The exporter's Employer Identification Number;

(iii) The names and telephone numbers of contact persons for the exporter and the recipient;

(iv) The quantity, calculated level, and type of controlled substances exported, and what percentage, if any, of the controlled substances are recycled or used;

(v) The source of the controlled substance and the date purchased;

(vi) The date on which and the port from which the controlled substances were exported from the United States or its territories;

(vii) The country to which the controlled substances were exported;

(viii) The bill of lading and the invoice indicating the net quantity of controlled substances shipped and documenting the sale of the controlled substances to the purchaser; and

(ix) The commodity code of the controlled substance exported.

(2) The Administrator will review the information and documentation submitted under paragraph (a)(1) of this section, and will assess the quantity of controlled substances (other than recycled or used controlled substances) that the documentation verifies were exported. The Administrator will issue the exporter consumption allowances equivalent to the calculated level of

[1] **Editorial note:** Section 82.12 is currently reserved. The Environmental Protection Agency will add regulations in that section at a future date.

controlled substances that the Administrator determined were exported. The grant of the consumption allowances will be effective on the date the notice is issued.

(b) No consumption allowances will be granted after January 1, 1993, for exports of controlled substances to any nation not listed in Appendix B to this Part (Parties to the Montreal Protocol).

§ 82.11 Exports to parties.

In accordance with the provisions of this section, any person may obtain authorization to convert potential production allowances to production allowances by exporting controlled substances to nations listed in Appendix B to this part (Parties to the Protocol). Authorization obtained under this section will be valid only during the control period in which the controlled substances departed the United States or its territories. A request for authorization under this section will be considered a request for consumption allowances under § 82.10, as well.

(a) The exporter must submit to the Administrator a request for authority to convert potential production allowances to production allowances. That request must set forth the following:

(1) The identities and addresses of the exporter and the recipient of the exports;

(2) The exporter's Employee Identification Number;

(3) The names and telephone numbers of contact persons for the exporter and for the recipient;

(4) The quantity, the calculated level, the type of controlled substances exported, its source and date purchased, and what percentage, if any, of the controlled substances that are recycled or used;

(5) The date on which and the port from which the controlled substances were exported from the United States or its territories;

(6) The country to which the controlled substances were exported;

(7) The bill of lading and invoice indicating the net quantity shipped and documenting the sale of the controlled substances to the purchaser; and

(8) The commodity code of the controlled substance exported.

(b) The Administrator will review the information and documentation submitted under paragraph (a) of this section, and assess the quantity of controlled substances (other than recycled or used control substances) that the documentation verifies were exported to a Party. Based on that assessment, the Administrator will issue the exporter a notice authorizing the conversion of a specified quantity of potential production allowances to production allowances in a specified control year, and granting consumption allowances in the same amount for the same control year. The authorization may be used to convert potential production allowances to production allowances as soon as the date on which the notice is issued.

§ 82.12 Transfers of production and consumption allowances [Reserved].

§ 82.13 Recordkeeping and reporting requirements.

(a) Unless otherwise specified, the recordkeeping and reporting requirements set forth in this section take effect as follows:

(1) For Group I controlled substances, beginning with the first day of the first control period specified in § 82.3(f)(1).

(2) For Group II controlled substances, beginning with the first day of the first control period specified in § 82.3(f)(2).

(b) Reports and records required by this section may be used for purposes of compliance determinations. The requirements of records and reports is not intended as a limitation on the use of other evidence admissible under the Federal Rules of Evidence.

(c) Unless otherwise specified, reports required by this section must be mailed to the Administrator within 45 days of the end of the applicable reporting period.

(d) Records and copies of reports required by this section must be retained for three years.

(e) In reports required by this section, quantities of controlled substances must be stated in terms of kilograms.

(f) Every person ("producer") who will produce controlled substances during a control period must comply with the following recordkeeping and reporting requirements:

(1) Within 120 days of the date this rule is published in the **Federal Register**, every producer must provide a report to the Administrator describing:

(i) The method by which the producer in practice measures daily quantities of controlled substances produced;

(ii) Conversion factors by which the daily records as currently maintained can be converted into kilograms of controlled substances produced, including any constants or assumptions used in making those calculations (e.g. tank specifications, ambient temperature or pressure, density of the controlled substance, etc.);

(iii) Internal accounting procedures for determining plant-wide production;

(iv) The quantity of any fugitive losses accounted for in the production figures; and

(v) The estimated percent efficiency of the production process for the controlled substance.

Within 60 days of any change in the measurement procedures or the information specified in the above report, the producer must submit the revised data or procedures to the Administrator.

(2) Every producer must maintain the following:

(i) Dated records of the quantity of each of the controlled substances produced at each facility;

(ii) Dated records of the quantity of controlled substances used as feedstocks in the manufacture of controlled substances and in the manufacture of non-controlled substances and any controlled substances introduced into the production process of new controlled substances at each facility;

(iii) Dated records of the quantity of HCFC-22 and CFC-116 produced within each facility also producing controlled substances;

(iv) Dated records of the quantity of the following raw materials and feedstock chemicals used at each plant for the production of controlled substances: carbon tetrachloride, perchloroethylene, chloroform, hydrofluoric acid, chlorine, bromine, CFC-113, HCFC-22, and CFC-23.

(v) Dated records of the shipments of controlled substances produced at each plant;

(vi) The quantity of controlled substances, the date received, and names and addresses of the source of recyclable or recoverable materials containing controlled substances which are recovered at each plant;

(3) For each quarter, each producer must provide the Administrator with a report containing the following information:

(i) The production by plant in that quarter of each controlled substance, specifying the quantity of any controlled substance used for feedstock purposes for controlled and non-controlled substances for each plant and totaled for all plants owned by the producer;

(ii) The calculated levels of production (expended allowances) for Group I and Group II controlled substances for each plant and totaled for all plants for that quarter and totaled for the control period to-date;

(iii) The shipments of each controlled substance from each plant in that quarter;

(iv) The producer's total of expended and unexpended consumption allowances, potential production allowances, expended and unexpended

production allowances and authorization to convert potential production allowances to production allowances, as of the end of that quarter;

(v) The quantity, the date received, and names and addresses of the source of recyclable or recoverable materials containing the controlled substance which are recovered at each plant; and

(4) For any person who fails to maintain the records required by this paragraph, the Administrator may assume that the person has produced at full capacity during the period for which records were not kept, for purposes of determining whether the person has violated the prohibitions at § 82.4.

(g) For Group I controlled substances, beginning with the first control period specified under § 82.3(f)(1), and for Group II controlled substances, beginning one year after the Montreal Protocol enters into force, importers of controlled substances during a control period must comply with the following recordkeeping and reporting requirements:

(1) Any importer must maintain the following records:

(i) The quantity of each controlled substance imported, either alone or in mixtures;

(ii) The date on which the controlled substances were imported;

(iii) The port of entry through which the controlled substances passed;

(iv) The country from which the imported controlled substances were imported;

(v) The port of exit;

(vi) The commodity code for the controlled substances shipped;

(vii) The importer number for the shipment;

(viii) A copy of the bill of lading for the import;

(ix) The invoice for the import; and

(x) The U.S. Customs Entry Summary Form.

(2) For each quarter, every importer must submit to the Administrator a report containing the following information:

(i) Summaries of the records required in paragraph (g)(1)(i)–(vii) of this section for the previous quarter;

(ii) The total quantity imported in kilograms of each controlled substance for that quarter;

(iii) The calculated levels of import (expended allowances) of Group I and Group II controlled substances for that quarter and totaled for the control-period-to-date; and

(iv) The importer's total sum of expended and unexpended consumption allowances at the end of that quarter.

(h) For any exports of controlled substances not reported under § 82.10 (additional consumption allowances) or § 82.11 (Exports to Parties), the exporter who exported the controlled substances must submit to the Administrator the following information within 45 days of the end of the control period in which the unreported exports left the United States:

(1) The names and addresses of the exporter and the recipient of the exports;

(2) The exporter's Employee Identification Number;

(3) The type and quantity of controlled substances exported and what percentage, if any, of the controlled substances that are recycled or used;

(4) The date on which and the port from which the controlled substances were exported from the United States or its territories;

(5) The country to which the controlled substances were exported; and

(6) The commodity code of the controlled substance shipped.

§ 82.14 Payment of fees [Reserved].

APPENDIX A

Controlled substance	Ozone depletion weight
A. Group I:	
CFC13—Trichlorofluoromethane (CFC-11)	1.0
CC12F2—Dichlorodifluoromethane (CFC-12)	1.0
CC12F-CC1F2—Trichlorotrifluoroethane (CFC-113)	0.8
CF2C1-CC1F2—Dichlorotetrafluoroethane (CFC-114)	1.0
CC1F2-CF3—(Mono)chloropentafluoroethane (CFC-115)	0.6
B. Group II:	
CF2BRC1—Bromochlorodifluoroethane (Halon 1211)	3.0
CF3BR—Bromotrifluoroethane (Halon 1301)	10.0
C2F4Br2—Dibromotetrafluoroethane (Halon 2402)	6.0

Appendix B—Parties to the Montreal Protocol [Reserved]

Appendix C—Nations Complying With, But Not Parties to, the Protocol [Reserved]

Appendix D—Twenty-Five-Kilotonne Parties [Reserved]

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Friday
August 12, 1988

Part IV

Environmental Protection Agency

40 CFR Part 82

Protection of Stratospheric Ozone; Advance Notice of Proposed Rulemaking

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL-3426-2]

Protection of Stratospheric Ozone

AGENCY: Environmental Protection Agency.

ACTION: Advance Notice of Proposed Rulemaking (ANPRM).

SUMMARY: EPA is considering further rulemaking on several issues related to its efforts to protect stratospheric ozone. In a separate notice published in today's **Federal Register**, the Agency issued final rules implementing the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol). In the context of that rulemaking, four issues were raised and action on them deferred pending additional public comment and review.

In the Preamble to its final rule, EPA briefly described new scientific information related to global ozone trends and seasonal losses in Antarctica. This ANPRM explains in greater detail the nature of that information.

EPA's final rule implements the Protocol through a system of allocated production and consumption allowances. EPA adopted this approach because, on balance, it appeared to be the most effective means of limiting ozone-depleting substances consistent with the Montreal Protocol. However, as explained in the preamble to the final rule, EPA is concerned about two unintended adverse consequences that might result from implementation of the rule.

By allocating allowances to the seven domestic producers of CFCs and halons, and by restricting future supply of these chemicals, EPA's regulation could result in sizable windfalls accruing to these producers. The existence of these windfalls could create an economic incentive for producers to delay the introduction of chemical substitutes which could have adverse economic and potential environmental consequences. EPA is seeking comment on the appropriateness and structure of supplementing its allocated quota system with a regulatory fee to remove any unintended incentives. Alternatively, the Agency is also seeking comment on the desirability of shifting from the allocated quota system promulgated today to an auction system.

While the theory behind the allocated quota system is that the marketplace, through price increases, will provide adequate incentive for firms to reduce their use of the regulated chemicals, EPA is concerned that some industries, particularly those in which CFCs and halons are a small part of the price of final goods, may be slow to respond to market-driven price increases and may not shift away from these chemicals as soon as it becomes cost-effective to do so. The effect of any such delays would be to substantially increase CFC and halon prices to all firms, to increase the total costs to society of meeting the Protocol's control requirements, and to increase windfalls to producers. EPA is seeking comment on industry-specific control requirements as a supplement to allocated quotas that, under certain circumstances, it might promulgate to ensure that needed reduction in the use of CFCs and halons are adopted as soon as these reductions are cost-effective.

DATE: Written comments on the ANPRM must be submitted by November 1, 1988, to the location listed below.

ADDRESSES: Written comments should be sent to Docket A-88-27, Central Docket Section, South Conference Room 4, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The docket may be inspected between 8 a.m. and 3:30 p.m. on weekdays. As provided in CFR Part 2, a reasonable fee may be charged for photocopying. To expedite review, it is also requested that a duplicate copy of written comments be sent to Stephen R. Seidel at the address listed below.

FOR FURTHER INFORMATION CONTACT: Stephen R. Seidel, Senior Analyst, Office of Program Development, Office of Air and Radiation (ANR-445), EPA, 401 M Street SW., Washington, DC 20460. Telephone (202) 382-2787.

SUPPLEMENTARY INFORMATION:

I. Background

The threat of depletion of the ozone layer from chlorofluorocarbons (CFCs) was first raised well over a decade ago by the scientific community (Molina and Rowland, 1974). The initial theory suggested that because CFCs are relatively inert, emissions of these chemicals would not break down in the lower atmosphere, but would instead slowly migrate to the stratosphere where they would then break apart releasing chlorine. Once freed in the stratosphere, the chlorine would catalytically destroy ozone. From a health and environmental perspective, depletion of the earth's ozone layer would allow more harmful ultraviolet radiation to penetrate the atmosphere and strike the earth's surface which would increase the incidence of certain skin cancers and cataracts, suppress the human immune system, damage crops and aquatic organisms, accelerate weathering of certain plastics, and increase formation of ground-level ozone (smog).

In the fourteen years of research since the original theory was proposed considerable scientific evidence has supported the general concern that increased emissions of CFCs (and halons) would lead to ozone depletion. (See, for example, Atmospheric Ozone, 1985 (WMO, 1986)).

In response to the growing scientific consensus, the United Nations Environment Program (UNEP) began negotiations in 1981 in an effort to develop a multilateral response to reducing the threat of ozone depletion. These negotiations resulted in the Vienna Convention for the Protection of the Ozone Layer in March 1985 which provides a framework for international cooperation in research, monitoring, and information exchange. Further negotiations resulted in the Montreal Protocol on Substances that Deplete the Ozone Layer which was signed in September 1987 and which requires Parties to reduce their use of specified ozone-depleting chemicals. The terms of the Montreal Protocol are discussed in detail in an earlier **Federal Register** notice (December 14, 1987; 52 FR 47489).

EPA's final rule implementing the Montreal Protocol is published elsewhere in today's **Federal Register.** The notice accompanying that rule summarizes the scientific, economic, technical, and legal bases for the Agency's action. It also describes the allocated quota system employed by EPA to achieve the Protocol's control refinements.

While EPA believes that its final action meets its obligations under Sec. 157(b) 42 U.S.C. section 7457(b) of the Clean Air Act and the Montreal Protocol, several issues were raised during the rulemaking which EPA believes require additional review.

Specifically, new scientific information became available in summary form during the course of the rulemaking which, in part because of time constraints, could not be fully reviewed and therefore was not considered in the final rule. This ANPRM provides the public with a summary of that information. EPA intends to notify the public of the availability of the full body of the Ozone Trends Panel Report (NASA, 1988) when it becomes available and will at that time request comments on its implications for future action.

Three other issues, which relate to unintended adverse consequences of EPA's use of allocated quotas, were

raised in the public comments on the proposal and warrant additional review. EPA is seeking comment whether it should add a regulatory fee to supplement the allocated quota system. The fee would be designed to capture the windfalls which would otherwise accrue to a small number of CFC and halon producers. EPA is concerned that the existence of such windfalls would create a potential economic incentive for these chemical producers to delay the introduction of chemical substitutes. Any such delay could have adverse economic and potential environmental impacts on EPA's stratospheric protection efforts. Alternatively, EPA is also seeking comment on the desirability of shifting at some future date to an auction-based system in place of allocated quotas.

Finally, EPA is also seeking comment on the desirability of developing industry-specific engineering controls and/or use-specific bans on CFCs. These rules are being considered as an adjunct to the allocated quota system, but would be promulgated only in instances where industries were not making timely progress toward reduced use of these chemicals.

II. New Scientific Information

A. Past Treatment

As part of its December 14 proposal, EPA discussed the existing evidence concerning possible changes that have already occurred to the ozone layer (52 FR 47492). It essentially stated that, based on the major assessment issued by the World Meteorological Organization in 1986 (WMO, 1986) and EPA's own risk assessment document (EPA, 1987), no statistically significant change had occurred in global estimates of total column ozone (i.e., the amount of ozone from the earth's surface through the stratosphere in any given place).

The preamble to the December proposal went on to discuss preliminary evidence related to areas of potentially critical concern: large seasonal losses in ozone over Antarctica (the so-called Antarctic ozone hole) and preliminary reports of global ozone reductions based on both ground-based and satellite measurements. While the existence of the ozone hole had been well documented by researchers, key questions remained: was it caused by man-made chlorine; are there health and environmental effects from this regional phenomenon; and are there implications for global ozone levels? Data suggesting that ozone had depleted globally had not yet been published in the scientific literature and therefore had not yet been thoroughly reviewed. In addition to validating and quantifying the trend itself, EPA also cited the need to distinguish ozone losses related to man-made chlorine from those related to natural causes (e.g., solar cycle, volcanic activity).

EPA also raised the concern that current atmospheric models which were relied on in the Agency's risk assessment do not account for these occurrences. In both cases, EPA stated that because of insufficient information and time, it was premature to consider these issues in its assessment of risks or as part of the rulemaking. The Agency also referenced an assessment of these issues (the Ozone Trends Panel) that was in progress at the time.

B. Summary Report of the Ozone Trends Panel

Following an 18-month review involving over 100 of the world's leading atmospheric scientists, the executive summary of the Ozone Trends Panel report was released on March 15, 1988. The Panel conducted an extensive review of existing ground-based and satellite measurements and of the results from recent campaigns to Antarctica. They analyzed and sought to isolate changes in ozone levels related to natural phenomenon from those related to chlorine and also compared ozone meausrements to predictions from atmospheric models.

The executive summary contains a listing of key findings. The analysis showed "undisputed observational evidence" of increased atmospheric levels of trace gases (CFCs, carbon dioxide, methane, nitrous oxides, halons) because of human activities. Its review of global ozone trends showed a depletion of 1.7 to 3.0 percent ozone loss between 1969 and 1986 at latitudes between 30 and 64 degrees in the northern hemisphere (where measurements are the most extensive). This decrease occurs after correcting for the effects of natural variation and is more pronounced in the winter than the summer. After comparing these measurements with model calculations, the report states that "The observed changes may be due wholly, or in part, to the increased atmospheric abundance of trace gases, primarily chlorofluorocarbons (CFCs)." The Panel determined that "it was not possible to obtain a sufficiently accurate trend in total ozone using Nimbus-7 satellite data alone because the rate of degradation of the diffuser plate cannot be uniquely determined." This problem in interpreting the raw data from the satellite to correct for instrument error restricted the Panel's ability to rely on this source of information for its conclusions.

In its review of data related to Antarctic ozone, it reconfirmed that "There has been a large, sudden, and unexpected decrease in the abundance of springtime Antarctic ozone over the past decade." The 1987 data showed that the ozone hole had both deepened (i.e, greater loss of ozone) and had lasted longer than previously recorded. It also reported apparent ozone decreases since 1979 of 5 percent or more at all latitudes beyond 60 degrees south throughout the year. It concluded, "The weight of evidence strongly indicates that man-made chlorine species are primarily responsible for the observed decrease in ozone within the polar vortex."

The executive summary of the report has been added to the public docket for this rulemaking. As stated above, EPA will notify the public in a **Federal Register** notice when the full report is completed and at that time will seek public comment. The Agency intends to use this information in the coming months to update its own risk assessment and will also examine any additional scientific information (e.g. papers presented at the ozone trends conference held in May 1988 in Snowmass, Colorado) that has recently became available.

III. Combining a Regulatory Fee With Allocated Quotas

In proposing to implement the Montreal Protocol (52 FR 47489; December 14, 1987), EPA examined a range of alternative regulatory approaches including the use of traditional engineering control requirements and innovative market-based rules, and stated that "[e]ach of the options has certain advantages, but also raises possible problems" (52 FR 47500). As explained in the notice accompanying the final rule, after reviewing the public comments, EPA concluded that, on balance, the allocated quota approach is the appropriate means of implementing the Montreal Protocol. However, EPA also noted that additional regulatory steps may be required to minimize any unintended adverse impacts resulting from this approach.

One such impact is the potential for current CFC and halon producers to reap a windfall profit from the scarcity created by EPA's regulation. In its December 14 notice of proposed rulemaking (NPRM), EPA asked "whether possible profits from continued production of the restricted chemicals might have the undesired

effect of delaying the introduction of less profitable chemical substitutes" (52 FR 474507). The Agency also asked for comments on the option of combining allocated quotas with a regulatory fee.

A. Basis for Adding a Fee to Allocated Quotas

EPA received public comment on both the likelihood of sizable windfalls resulting from its allocated quota system and the potential implications for delaying the introduction of chemical substitutes. The Agency also initiated two studies (DeCanio, 1988 and Sobotka, 1988) examining these issues.

1. Likelihood and Magnitude of Windfall

In the December 14 NPRM, EPA explained why windfall profits (also termed transfer revenues) could result from its proposed allocated quota system. Essentially, the allocated quota system operates by restricting the supply of CFCs and halons. Since demand for these chemicals by user industries is expected to continue to grow (because of continued demand for products which contain them or are made with them), competition for the restricted CFC and halon supplies should result in firms paying higher prices for these chemicals. While higher prices for CFCs and halons will stimulate some firms and industries to shift to alternate materials, institute or increase recycling, or produce other products, if substitutes are not readily available, many firms will have little choice but to continue to use these chemicals while paying a higher price.

The RIA supporting the December 14 NPRM estimated windfall profits of between $2–6 billion through the end of the century depending on the rate at which firms employed low-cost control technologies (i.e. the faster controls are employed the lower the windfalls). The amount of the predicted windfall is based on the market-clearing price paid for CFCs and halons. In turn, this price results from the allowable supply of CFCs and the market demand as determined, in part, by the costs of options available to firms and consumers to reduce their use of these chemicals.

EPA has revised its preliminary RIA to include new information on control technologies and market demand for these chemicals. Its revised estimate suggests that windfalls could range from $1.8 to $7.2 billion through the turn of the century. (See chapter 9 of the RIA.)

2. Potential for Delay of Substitutes

As stated in the December 14 NPRM, EPA is concerned that the existence of large windfalls could create an economic incentive for the CFC and halon producers to delay the introduction of chemical substitutes. Chemical substitutes are likely to be more costly to produce and therefore less profitable than CFCs and halons. In contrast, CFC and halon prices are likely to increase because of the supply restrictions set forth in EPA's regulation which could result in substantial windfall profits for CFC producers. As a result, EPA is concerned that the seven CFC and halon producers may use their market power to increase profits either by restricting the introduction of new chemicals by others or by delaying the introduction of the chemical substitutes they now have under development.

EPA is seeking public comment on whether markets conditions are likely to create an environment where such actions are possible. Factors affecting future market conditions include: who conducts research and development for new chemicals; who conducts research and development for user industry applications; what is the likely cost of chemical substitutes; and whether the CFC/halon producers can deter competition from outside parties.

Based on a review of patents on potential substitutes, it appears that the current producers of CFCs and halons are also the most likely producers of alternatives (Radian, 1987). For example, patents for HFC–134a and HCFC–123, two of the most likely substitutes, are held by several CFC producers in the United States as well as by CFC producers in other countries. Moreover, a large share of the products applications testing for many industries using CFCs is done by the chemical producers. These companies provide a wide range of services to their customers including detailed tests on the applicability and use of new chemicals.

Estimates of the costs of producing chemical substitutes generally range from 2–4 times the costs of the currently available CFCs (Nelson, 1988). This large difference in the costs of production between the current CFCs and their substitutes suggests that CFC producers may have considerable flexibility in pricing CFCs to respond to efforts by non-producers to capture markets with more expensive chemical substitutes.

Whether chemical producers will use this incentive to delay the introduction of chemical substitutes to increase windfall profits will depend on the extent to which they are willing and able to pursue a strategy of profit maximization. One public interest group in their comments on the December proposal contended that firms typically base decisions concerning the timing of new product introductions on such factors as the goal of maximizing profits on existing products. The following discussion indicates that CFC producers may have the *ability* to pursue such a goal; moreover, with the large potential windfall, it is clear that they will have an economic *incentive* to do so.

In most market situations, the company first to introduce a new product has the advantage. In this particular situation, however, 14 major chemical firms from throughout the world are working together as part of a private consortium in conducting joint toxicity tests. This joint effort offers many important advantages. It spreads the multi-million dollar costs of conducting these tests among many participants. It maximizes the use of the limited quantities of the new chemicals available for all purposes (toxicity tests and user application tests) in the near term. However, a public interest group in its comments raised the issue that this joint effort effectively creates a potential mechanism for these firms to delay or slow down the introduction of new chemicals by influencing the pace and extent of toxicity testing. Thus, in the current market situation, the producers of CFCs are the owners of the most likely substitute technologies (e.g., through patents and proprietary process information) and could through the joint toxicity testing program and the high capital costs of production, be able to control the rate of diffusion and adoption of substitutes.

Future increases in CFC prices will also provide an incentive for non-CFC producers to develop and market substitutes. However, these firms will be at a disadvantage for several reasons. As previously suggested, they generally lack the research, technical and marketing foundation to compete against current CFC producers. Moreover, current CFC producers could attempt to counter the introduction of substitutes by others by reducing the market price of CFCs (and thereby reduce but not eliminate their windfalls).

EPA believes that a regulatory fee, by capturing the windfall profits, would remove the economic incentive for delay and thus at least partially address these concerns.

3. Impact of a Two-Year Delay

The revised RIA supporting the final rule examines the potential impact of delaying by two years the introduction of chemical substitutes. This analysis, as shown in Table 1, compares the impact of different schedules for the introduction of chemical substitutes on the costs and feasibility of meeting the

reductions called for in EPA's regulation. It illustrates several critical points. First, it shows that the effect of delaying the marketability of chemical substitutes is closely related to the rate at which firms act to adopt low-cost control options. Not surprisingly, the amount of pre-tax windfall, as well as the cost increases resulting from the delay of chemical substitutes, is substantially greater in Case 1 than in the other two cases. Case 1 represents a scenario in which major user industries (e.g., mobile air conditioning, solvent uses, hospital sterilization, refrigeration and certain foam uses) delay their adoption of technically available, low-cost reduction options. Table 1 shows that windfalls through the end of the century would *increase* by $10 billion through the end of the century under this scenario if the introduction of substitutes were delayed by two years. The potential increase in windfalls for producers from a two-year delay were estimated to be $1.3 billion in the Case 1A+B (where two industry segments aggressively employ reduction technologies) and $100 million in Case 2 which represent a scenario where user industries adopt technologically feasible, low-cost controls in a more timely manner. Table 1 also shows that windfalls in the early years could be quite substantial (case 1) or could be eliminated completely if low cost options are actively adopted (case 2).

TABLE 1.—IMPACTS OF A TWO-YEAR DELAY IN THE AVAILABILITY OF CHEMICAL SUBSTITUTES [a]

	Case 1 [b]		Case 1A+B [c]		Case 2 [d]	
	Without delay	With delay	Without delay	With delay	Without delay	With delay
Social Costs: [e] 1989–2000	2,730	4,252	2,122	2,215	1,012	1,033
Transfer Costs: [f] 1989–2000	7,282	17,390	4,983	6,329	1,886	1,985
CFC Price Increases: [g]						
1989	6.69	6.69	1.95	1.95	0.00	0.00
1990	5.32	5.32	1.84	1.84	0.00	0.00
1991	1.84	5.88	1.59	1.85	0.00	0.00
1992	1.60	5.88	1.55	1.95	0.00	0.00
1993	3.93	[h] 50.00	3.55	10.84	1.55	1.84
1995	5.48	5.00	3.55	3.77	1.59	1.59
1998	5.48	17.69	5.48	5.48	4.49	4.49
2000	5.48	5.48	5.48	5.48	3.77	4.35

[a] The assumed stringency and coverage assumptions used are those of the CFC 50%/Halon Freeze case described in Chapter 5 of the RIA. CFCs are regulated with an initial freeze in 1989 at 1986 levels, 20 percent reduction in 1993, and 50 percent reduction in 1998, and halons are frozen at 1986 levels in 1992. The assumed rate of growth in baseline use is the Middle Growth Scenario described in Chapter 4 of the RIA.

[b] Case 1 assumes that firms do not act expeditiously to employ cost-effective control options. For specific control options that are delayed, see Chapter 9 of the RIA.

[c] Case 1A+B assumes that reductions from recycling of car air conditioners and shifts to alternative solvents are initiated in the initial years of the regulation, but that other sectors delay their adoption of cost-effective reductions. See Chapter 9 of the RIA.

[d] Case 2 assumes control reductions are adopted across several key industries as explained in Chapter 9 of the RIA.

[e] Social costs discounted at a 2 percent discount rate and cited in millions of 1985 dollars. All windfalls are stated before taxes.

[f] Transfer payments discounted at a 6 percent discount rate and cited in millions of 1985 dollars.

[g] Price increases are for all CFC compounds and are stated in dollars per kilogram are weighted by ozone depletion potential and are cited in constant 1985 dollars. CFC prices are currently about $1 per kilogram.

[h] CFC price increases are capped at $50.00 which indicates that insufficient controls or substitutes are contained within the model to achieve the required reduction.

Table 1 also illustrates a second point. It shows that in Case 1, a two year delay renders it significantly more costly and difficult to meet the 20 percent reduction stage in 1993. The $50.00 CFC price increase which occurs in that year is a "backstop" price indicating that, based on current information, no alternative technologies are available to achieve the required reductions. In the absence of technologies or substitutes to reduce CFC use to the required levels, the economic hardship and dislocations in meeting the required reductions would be severe. The dealy in the availability of chemical substitutes would also make it more difficult to obtain greater or further CFC and halon reductions in the future, should new scientific information lead to a change in the Protocol's control requirements.

This analysis likely underestimates the additional costs associated with delays in introducing chemical substitutes by ignoring potential savings that are likely as firms start "learning by doing" earlier rather than later (Decanio, 1988). This potential savings reflects the likely reductions in cost over time that will occur as producers and users gain experience with the chemical substitutes.

A regulatory fee could also indirectly aid in efforts to encourage developing nations to join the Protocol. One goal of the Protocol is to avoid expanded production of CFCs by these nations. To accomplish this end, the Protocol allows limited increases in production of controlled substances in developed nations if they are exported to developing nations. Because of the technological ease of CFC production, developing nations may choose to produce CFCs themselves and not to join the Protocol if CFC substitutes are not readily available. Further, over the longer term, developing nations are more likely to participate in the protocol if they can themselves produce the chemical substitutes required for their domestic industries (e.g., refrigeration, electronics, etc.) which now use CFCs. Thus, the timing of the availability of chemical substitutes will be one key factor in decisions by developing nations to join the Protocol.

4. Summary of Public Comments

Seven commenters (auto companies, federal agency, public interest groups) stated that they opposed the use of allocated quotas alone because it would result in a small number of producers reaping substantial windfalls and allow them to exercise substantial power over user industries through control of CFC supplies. Some of these commenters also raised concerns about the possibility of producers cutting production further than the regulations require (to further increase prices) or delaying the introduction of chemical substitutes.

Ten commenters (public interest groups) stated that they supported the use of a regulatory fee because if would provide an added incentive for firms to reduce their consumption of CFCs and halons and would capture the windfall profits that might otherwise encourage

producers to delay the development of chemical substitutes.

In contrast, six commenters (chemical producers and industry trade association) argued that EPA had overestimated the magnitude of likely windfalls. As stated earlier, EPA's Regulatory Impact Analysis (RIA) supporting the proposed regulation stated that, depending on the rate at which firms shifted away from CFCs and halons, the magnitude of windfalls would range from just under $2 billion to just under $6 billion (pre-tax dollars) over the remainder of this century. The commenters suggested that this estimate failed to consider the higher costs associated with reduced CFC production, the increase in government tax receipts from any windfalls, and the need for capital to fund development of chemical substitutes. Several commenters also stated that because chemical producers are likely to allocate their allowable production to past customers and therefore are not likely to charge full market price for CFCs and halons, windfalls would be lower than EPA's estimate.

The Agency's reexamination of its analysis in light of the public comments has reaffirmed its general conclusions on the magnitude of the potential windfalls. The Agency recognizes that fixed costs may increase slightly as production is cut; however no evidence has been presented demonstrating likely increases in variable costs which represent by far the largest percent of total production costs. As a result, production costs are not likely to increase substantially in future years. While the RIA presents estimates of transfers in pre-tax figures, EPA recognizes that to determine a firm's actual windfall profits, the figures presented would have to be adjusted to reflect each firm's marginal tax rate. EPA's estimate of CFC price increases and transfers were similar to those contained in an industry-sponsored analysis (performed by Putnam, Hayes and Bartlett for the Alliance for Responsible CFC Policy, 1987) of the impact of the proposed rule.

EPA also questions the assertion by some chemical producers that they intend to moderate price increases and allocate their supplies to past customers which would have the effect of reducing windfalls. Although firms can point to past situations of shortages where supplies have been rationed (instead of sold at a market-clearing price), these situations typically involve only minor and temporary shortfalls in supply. In the case of CFCs, shortages are likely to increase over time and, unless regulations change, are permanent. The use of allocations by producers to their customers would substantially reduce the potential profits from these chemicals to the producers. In addition, if a secondary market developed, users for which current CFCs are less important or which can utilize existing substitutes or can recycle ("elastic" users), would have an incentive to sell some of their allocation to users with little flexibility ("inelastic" users) at higher prices than they paid for the CFCs. Thus, these "elastic" CFC users would capture much of the windfall for themselves. Mindful of this, there is a strong incentive for the producers to recoup the windfalls themselves rather than see their customers the beneficiaries of these profits. Moreover, any allocation of these chemicals would likely result in substantial economic inefficiencies unless a secondary market quickly developed. If allocated CFCs or halons, user frims with relatively inexpensive reductions would have less of an incentive to make such reductions, while firms without such options would have a more difficult time in purchasing CFCs or halons. The net effect of an allocation by producers would be a substantially greater cost to society to achieve any given reduction (Decanio, 1988).

EPA also strongly disagrees with some commenters arguments that windfalls are necessary to fund the development of chemical substitutes. This argument suggests that price increases for the current CFCs should be used to subsidize specific firms (i.e., the current CFC and halon producers) to develop alternatives. EPA believes that, at least in the medium and long-term, many firms besides the current CFC and halon producers are capable of developing substitutes, and that all such firms should have equal opportunity to bring substitute chemicals to the marketplace. Investment decisions concerning the development of new chemicals by existing CFC and halon producers should be based on market potential and not indirectly subsidized by EPA regulations.

EPA's analysis contained in the RIA also suggests that the amount of the windfall profits (e.g., several billion dollars) is far in excess of the resources now being spent by the chemical producers for research on chemical substitutes. Morover, there would be no guarantee that producers would channel their windfalls back into the development of alternative chemicals. Finally, given the substantial market for alternatives to CFCs, EPA does not agree that any such subsidy is necessary or warranted.

Many industry commenters (primarily foam-blowers and halon users) opposed the use of a fee system they believed it would increase the cost of the regulated chemicals and thus their costs of doing business, and would also make it difficult to compete against product substitutes particularly in some foam areas.

EPA does not believe that a fee, used in conjunction with allocated quotas, would necessarily alter the price of CFCs and halons to user industries. As discussed above, the price of these chemicals is determined by supply and demand. As a result, the price should increase over time because of the scarcity created by the limits on production contained in the allocated quota regulation; consequently, all user firms will pay somewhat higher prices over time if they want to continue using these chemicals. By setting the fee at or below the market price increase resulting from the reduced availability of these chemicals (i.e., the price increase which results from the scarcity created by allocated quotas), no further increase in the price of CFCs or halons should occur. The fee would, however, reduce or eliminate the amount of windfall profits to the producers and capture that revenue for the United States Treasury, therefore eliminating any potential economic incentive to delay the introduction of less profitable chemical substitutes.

Some users appear to believe that producers will simply pass on the additional costs of the fee to the user industries, in effect charging them both the price increase due to the scarcity created by the allocated quotas and the added costs of the fee. If producers attempted to do so, the forces of the marketplace would operate to reduce demand for CFCs and halons below the level of their allocation. Thus, producers would see the additional profits they would earn on CFCs sold at a higher price offset by the foregone profits from lost sales. However, under a fee system which captured the entire windfall (e.g., a fee based on the difference between observed market price and production costs) producers would never benefit from attempting to pass the fee on to users.

B. Design of Fee With Allocated Quota System

Table 1 shows the amount of CFC price increases for different scenarios. These increases would effectively be the same as the rate at which a fee would be assessed if all the windfalls were

captured and production costs remain unchanged. The table shows that the magnitude of the fee (or CFC price increase) depends on the rate at which firms reduce their consumption of CFCs. In fact, in Case 2, where firms in many sectors act quickly to reduce CFC consumption, no fee would be expected in the initial years of the regulation.

The December 14 NPRM briefly described issues related to the design of a regulatory fee. Design parameters mentioned included phasing-in the fee, basing the fee on the relative ozone depletion weights of the different chemicals, and adjusting the fee over time (e.g., to reflect changes in market conditions, regulatory requirements, etc.).

EPA received few comments on specific design issues. A chemical manufacturer and an auto company stated that, because of the limited detail contained in the December NPRM, any fee schedule would require additional public notice and comment including review at a public hearing. The chemical producer also stated that the CFR and Halon price increases contained in EPA's RIA analysis were sufficiently flawed that they should not be used as the basis for setting a fee. EPA agrees with these comments; additional analyses, public review and comment are necessary before a regulatory fee can be adopted.

Although EPA has concerns, discussed below, about whether it has the authority and administrative capacity to design and administer a large fee program, the following sections discuss specific design issues related to implementing a regulatory fee program. The fee system should be narrowly circumscribed to further the regulatory purpose in section 157(b), (or TSCA Section 6, if TSCA is used as the authority for the fee). EPA believes that the following methods of setting a fee further the purpose of that section, but is seeking comments on all issues related to its use of a regulatory fee.

1. Setting a Fee

In evaluating options for setting a fee, EPA has considered a number of issues, relating to the design and administration of the fee.

(i) When does a windfall profit arise? Specifically, producers legitimately expect a "regular" (non-windfall) profit—*i.e.*, a reasonable rate of return. How should the Agency determine when profit margins exceed the reasonable rate of return as a result of the Protocol/EPA restrictions?

(ii) How should the windfall profit be computed? In general, the windfall profit is the difference between (a) market price and (b) costs plus reasonable rate of return. How should the Agency compute each element? For example, should EPA use actual current market price and actual costs, and actual rate of return during the pre-Protocol period (when no restrictions applied and thus no windfall profit situation existed)? Or, should EPA use proxies for some or all of these elements?

(iii) Should EPA's fee try to capture some or all of the windfall? What are the advantages and disadvantages of trying to capture the entire windfall?

(iv) How would EPA administer the fee? For example, what collection procedures would be necessary? What types of appeals could be expected between EPA and the industry, and by what administrative mechanism could those appeals be resolved? Note that these administrative concerns may vary, depending on how the fee is designed.

2. Options for Fee Design

a. Predetermined Escalating Fee Schedule. EPA could establish in its rule a set fee schedule which would escalate over time to reflect the expected increasing market price of CFCs and halons (as demand for these chemicals increases over time, but supply is reduced by EPA's regulation). In setting a fee schedule, EPA would also consider the expected costs and timing of the intoduction of new chemical substitutes which would act as a ceiling on potential CFR and halon price increases.

A predetermined fee schedule has the advantage of providing clear market signals for both producers and users. Depending on the level at which the fee was set, it also could remove much but probably not all of the potential for windfalls. It has the important disadvantage of being inflexible to new technological developments that could significantly influence future market conditions.

Based on EPA's existing analysis of control costs and chemical substitutes as explained in the RIA, the regulatory fee could be set at approximately $.25 per kg in the initial stage of the program and increase in a linear manner to approximate the currently anticipated costs of chemical substitutes (about $5.40/kg) in 1993 when they are expected to become available.

b. Fees Based on Model Predictions. EPA would initially set the fee based on (i) predicted market price, determined directly from the analysis contained in its RIA (which would be periodically updated); and (ii) estimated production costs (plus a reasonable rate of return), determined by a calculated baseline production cost periodically modified to reflect inflation and changes in the price of raw materials. For predicted market price, the Agency could use the average of its Case 1 and 2 scenarios (see Table 1) (which spans the likely response by industry) or it could develop a "most likely scenario." For estimated production costs, EPA could determine the production costs in a base year (e.g., a year before the Protocol came into effect) plus the profits earned that year. EPA could then index these numbers (costs plus profits) for inflation and changes in the price of raw materials. The windfall would be the difference between the predicted market price and the estimated production costs.

By estimating the market price *increases* in CFCs and halons, the RIA model theoretically predicts the amount of the windfalls assuming no changes in production costs. However, given the complexity of the analysis, the control cost model used in the RIA could predict increases that are either too high or too low. EPA may want to base the fee on some percentage of its estimated price increase (e.g., 90 or 95 percent) to avoid imposing a fee higher than the windfall that would directly result from the forces of supply and demand. In addition, as new information becomes available, the analysis would have to be periodically updated to reflect actual market responses.

If the analysis contained in the current RIA were used to set the amount of the fee and the fee were based on 100 percent of the average of Case 1 and 2 scenarios and assuming no changes in production costs, (i.e. no indexing of production costs plus a reasonable rate of return), the fee amounts would be the following:

Year	Projected CFC price increase [1]
1989	$3.39
1991	0.92
1993	2.66
1995	2.68
1999	4.99
2000	4.62

[1] Assumes no change in production costs and no increase in reasonable rate of return.

c. Adjustable fees based actual market price. Under this approach EPA would base the fee on (i) actual market prices of CFCs and halons and (ii) either actual or estimated production costs (plus a reasonable rate of return). As in the last option, if production costs were esitmated, a base year prior to the Protocol restrictions would be selected. For example, if production costs were estimated using 1986 as the base year, the difference between the 1986 market

price charged by CFC and halon producers for the controlled substances and the price charged in the marketplace for these chemicals after the allocated quota system were implemented would be used to determine the fee. Future market prices would be used in determining the amount of the fee. Future market prices would be used in determining the amount of the fee to ensure that the net prices (i.e., reflecting any increases in production costs) received by CFC producers were constant. Under this approach, future production cost increases could be calculated based on an inflation index and published prices for feedstocks chemicals. Instead of estimating changes in production costs, EPA could determine actual production costs, plus the reasonable rate of return in the base year, in order to calculate windfalls.

Basing the amount of the fee on observed prices would relieve EPA of the burden of attempting to forecast price changes. This approach would also likely result in a fee that fluctuates, as market prices change to reflect the introduction of new chemical substitutes. One likely outcome is a fee that is first higher and then lower. In the initial years of the phased reduction of CFCs, the price of CFCs is likely to increase up to the price level set by supply and demand as a result of the scarcity created by the allocated quotas. In the years following the introduction of chemical substitutes, the market price is likely to decrease as producers improve the efficiency of making these chemical substitutes and as users make more efficient use of them. Thus, the amount of the fee would be contingent on the amount of the CFC increase in price; only as long as the marginal costs of the chemical substitutes exceed the marginal costs of the CFCs, a fee be charged. This indicates an automatic "sunset" provision in the fee structure; the fee is self-extinguishing as substitutes become cheaper to produce over time.

This approach to setting a fee would effectively eliminate windfalls and thus remove any economic incentive producers may have to increase revenues from sales of existing CFCs or halons by withholding the supply of chemical substitutes. As a result, this approach effectively removes any economic incentive to delaying the introduction of chemical substitutes and thus is the approach most preferred by EPA.

3. Issues Related to Implementation of a Fee

EPA is also seeking public comment on whether the fee should be assessed against production, or against consumption (defined in the Protocol as production plus imports minus exports) of controlled substances. A fee on production alone would entail charging domestic producers for CFCs produced (including those exported), and would not impose charges on CFCs imported. This would increase costs only to domestic producers and would result in imports having a competitive advantage over domestic production and United States exports facing a competitive disadvantage vis-a-vis foreign production. A fee assessed against consumption would amount to a charge on all CFCs produced and imported, with an exemption or credit for CFCs exported. Allowing exports to be exempt from the fee would avoid burdening industry in the United States in its competition abroad without undermining the effectiveness of the fee program. A fee on consumption would be assessed against the limited number of producers and importers and not involve the collection of fees from the thousand of firms who use (but do not produce or import) controlled substances.

4. Uses of Revenue From a Fee

The goal of any regulatory fee under section 157(b) of the Clean Air Act or under Section 6 of the Toxic Substances Control Act would be to remove the incentive for delaying the introduction of chemical substitutes by reducing the size of windfall gains to producers. Under 31 U.S.C. 3302(b), any revenues generated from the assessment of a fee would go directly to the United States Treasury.

Because of this legal limitation, EPA is not considering a program to channel some portion of the estimated potentially multi-billion dollars in windfalls back to those industries developing or employing reduction technologies for CFCs and halons. Any such program could only be authorized directly by Congress. While allowing the CFC and halon producers to maintain the windfall profits themselves would be clearly inequitable, making some portion of the windfalls available to any firm developing or using reduction technologies might be potentially attractive in aiding the transition away from CFCs and halons. Resources might also be made available to groups of firms or associations working toward removing the institutional barriers (e.g., codes and practices, purchasing specifications) to shifting away from CFCs and halons. EPA is seeking public comment on the desirability of providing funding for the development of alternatives to CFCs and halons, how such program might be structured, and what legislative action would be necessary.

IV. Auctions

In it December 14 NPRM EPA also asked for comment on the use of auctions as the mechanism for allocating production and consumption allowances. In that notice, EPA stated several advantages of auctions. Specifically, an auction system should result in reductions being achieved in an economically efficient manner and any revenues from the auction would to directly to the United States Treasury.

Auctions are attractive, in part, because they provide a direct mechanism to ensure that the available CFCs and halons are awarded to he highest value uses. Through the bidding process, individual firms must determine how much they value the use of these chemicals. By awarding CFCs and halons to the highest bidders, this system ensures that the limited supply of these chemicals are put to their most economical uses. A major advantage of an auction is that it automatically yields a price for production and consumption allowances that reflects the expected windfall. Under an auction system, each bidder has the incentive to bid as close as possible to the expected value of the allowances. Firms that underbid at an auction could obtain fewer allowances than desired; firms that overbid would either pay a price greater than the value it placed on the allowances or would obtain more allowances than desired.

As discussed in the prior section in the context of adding a fee to allocated quotas, auctions would avoid the problems associated with potential billion dollar windfalls which would accrue to a handful of CFC and halon producers under allocated quotas alone. The revenue from higher CFC and halon prices which result from restricting supply of controlled substances as called for by the Montreal Protocol would instead be transferred to the Treasury through the auction system.

Because of these potential advantages, EPA is seeking additional public comment on the possibility of shifting sometime in the future from the allocation scheme contained in its final rule to one in which production and consumption allowances would be auctioned to any interested party. EPA intends to make such a determination within 90 days of the end of the public

comment period. If the Agency pursued this option, it would issue a notice of proposed rulemaking seeking public comment on a specified deadline for shifting from allocated quotas to auctions and specific changes in its rule to allow for such a shift, and would then issue a final decision on whether to provide for auctions.

A. Public Comments on December NPRM

A large number of industry commenters, including both CFC producers and user firms, argued against the use of an auction on the basis that it would result in greater market uncertainty, and encourage speculation and hoarding. CFC producers asserted that auctions would lead to: higher prices due to speculation and hoarding; increased uncertainties concerning production planning by allowing any person to hold production allowances; and a disincentive for the production of chemical substitutes by unnecessarily disrupting user markets. Producers also commented that problems associated with auctions were likely to be worse in the early years following implementation.

With the exception to some firms within the automobile industry, CFC and halon user industries also strongly opposed auctions. These firms were primarily concerned that firms would purchase more of these chemicals than they otherwise needed, thereby driving up prices. They were also concerned that speculators would enter the market, further adding to market uncertainties. Commenters asserted that problems of an auction could harm small firms disproportionately. They argued that such firms could be "shut-out" or outbid by large firms.

In contrast, several commenters supported the use of auctions as economically efficient and as a means of avoiding large transfers to producers which would result from simply allocating quotas based on past activity. One commenter argued that speculators would help stabilize the market by buying up allowances when prices were low and selling when prices are high. The commenter also stated that successful participation in an auction would be based on the value of CFCs to a firm and not on the size of a firm. To the extent that these may be problems, such difficulties are likely to be eliminated overtime through market transactions.

Several commenters stated that EPA had not provided sufficient detail in its description of an auction to permit adequate review and comment and therefore could not issue a final action without seeking additional public input. Several also questioned EPA's legal authority for implementing and auction. These legal issues are discussed below, in section V.

EPA has reviewed the public's response on this issue, and is seeking additional comment on possible ways to structure an auction system which would address the problems raised by commenters.

B. Structure of an Auction System

1. *Participation rules.* EPA believes that auctions should be open to all interested parties. Any limits on participation (e.g., only users, producers) would unnecessarily disrupt market forces.

While the auction would be open to all interested parties, EPA does not believe that most of the tens of thousands of firms who use CFCs and halons are likely to directly participate. These firms are more likely to continue using their current channels of supply (e.g., wholesalers and chemical producers) and rely on these firms to ensure that requirements for production and consumption allowances have been satisfied. Because of the limited participation by small users, EPA does not believe that the administrative costs associated with an auction would be excessive.

2. *Defining the commodity.* To implement the Montreal Protocol's limits on both production and consumption, separate auctions could be held for consumption and production allowances. Firms interested only in importing controlled substances would likely bid only on consumption allowances. Producers of controlled substances would likely bid on both production and consumption allowances. Producers could also rely on their customers to supply the consumption allowances also required for production under the Montreal Protocol.

All allowances would be transferable to provide firms maximum flexibility to respond to changes in market conditions. The allowances could also be for a single control period or they could allow the same amount of production or consumption for each of one or more periods (e.g., 100 units for each of the control periods covering 1988 and 1989). To ensure that the United States complies with the terms of the Montreal Protocol (which requires Parties to stay within limits defined in terms of 12-month control periods), allowances could be defined for multiple control periods, as long as they did not allow trade-offs between periods.

Allowances of a shorter duration would also reduce concerns that allowance holders, who are likely to include producers of CFCs and halons, might have an economic incentive to delay the introduction of chemical substitutes in order the maximize their market position.

To be consistent with the Montreal Protocol, all allowances would be defined in terms of Group I (CFCs) and Group II (halon) controlled substances and separate auctions would be held for each.

3. *Frequency of auctions.* The frequency of auctions could be an important factor in minimizing concerns raised about the possibilities of uncertainty and hoarding. Frequent auctions would help establish a market price, which would reduce uncertainties concerning the price or controlled substances. They would also ensure that a supply of CFCs is continuously made available to the public and thereby avoid concerns about hoarding.

4. *Bidding system.* To minimize administrative costs, the auction itself would likely be held through the mail. Firms would base their bids on the value to them of using controlled substances, which would be determined, in part, by the costs of alternative controls and technologies. Sealed bids would also minimize any gaming (e.g., bids based on competitor's actions) which could occur through public bids. Firms could submit as many bids as they want.

5. *Basis for Awards.* Awards would go to the highest bidders until all of the allowances up for auction are distributed. Under different auction systems, the price charged to the winning bidders may vary. Under one system all winning bids pay the amount contained in their bid. Under an alternative approach, each successful bid would pay an amount equal to the highest unsuccessful bid.

C. Public Comment

EPA is seeking public comment on the desirability of shifting from the promulgated allocated quota system to a regulatory system based on auctions, and on ways to minimize any disruption associated with such a shift. It is also seeking comment on the specific auction design features presented above.

V. Legal Issues Related to Fees and Auctions

In the December 13 NPRM, EPA specifically sought comment on the legality of adopting a regulatory fee or an auction (52 FR 47508). Numerous commenters (chemical producers and industry trade association) stated the

EPA does not possess the authority to use a fee or an auction. They argued that such a charge—a fee or an auction—would in effect constitute a tax and EPA does not possess the power to tax under the Clean Air Act or the Toxic Substances Control Act. In contrast, two commenters (federal agency and public interest group) stated that EPA did have the authority to use fees or auctions.

While EPA believes that CFC charges make good policy sense to eliminate any windfall that may arise, EPA recognizes that imposing CFC charges would be a novel interpretation of the environmental statutes. This action would represent regulatory action by an administrative agency, pursuant to an asserted, but not explicit, grant of authority from Congress, to collect charges. The sections below discuss the extent to which CFC charges would be legally permissible.

Two statutes that EPA administers provide possible legal authority: The Clean Air Act provides for the regulation of substances that may affect the stratosphere. Section 157(b) of the Clean Air Act describes the regulatory authority:

> [T]he Administrator shall propose regulations for the control of any substance, practice, process, or activity or any combination thereof) which is his judgement may reasonably be anticipated to affect the stratosphere, especially ozone in the stratosphere, if such effect in the stratosphere may reasonably be anticipated to endanger public health or welfare. Such regulations shall take into account the feasibility and the costs of achieving such control.

In addition, the Toxic Substances Control Act ("TSCA") provides for the regulation of toxic substances. Section 6(a) of TSCA provides that, after finding that a substance presents an unreasonable risk of injury to health or the environment—

> [T]he Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements . . . (5) A requirement prohibiting or otherwise regulating any manner of method of commercial use of such substance or mixture.

A third possible source of authority is the Independent Offices Appropriation Act ("IOAA") 31 U.S.C. 9701(a), which authorizes agencies to impose fees when granting benefits to outside parties.

Conscious that it may be breaking new ground, EPA is soliciting comments on the legal rationale for administrative charges in this context. EPA sees two sets of legal issues: The first are Constitutional issues, including (i) whether the administrative charges are "taxes" (i.e., whether the asserted grant of congressional authority represents a delegation of the Congress' authority under the Constitution to impose taxes [1]) or "fees" (i.e., whether the grant of authority represents a delegation of the authority to regulate commerce [2]); and (ii) whether any delegation of authority from Congress to EPA to impose charges under the CAA or TSCA was sufficiently circumscribed to avoid delegation-of-legislative-power questions. The second set of issues involve statutory interpretation, i.e., whether Congress in fact delegated authority to EPA under the CAA or the TSCA to impose these charges.

A. Constitutional Issues

1. Summary of Case Law

Three Supreme Court cases, and the series of appellate court cases that follow them, raise the Constitutional issues EPA is considering. In *National Cable Television, Inc.* v. *United States*, 415 U.S. 336 (1974) ("NCTA"), the Supreme Court construed the IOAA, and held that under this statute an agency may not impose a charge in excess of the value of agency services or other action to the recipient because such a fee would be a "tax." The Court defined a tax as a charge that has no necessary relationship to benefits received, may be based solely on ability to pay, and may be designed to serve public policy by, e.g., discouraging certain activities or preventing "entrepreneurs from exploiting a semipublic cause for their own personal aggrandizement." By comparison, according to the Court, a "fee" connotes some benefit, and is incident to a voluntary act such as a request for a permit. *NCTA*, at 341.

In *Head Money Cases (Edye* v. *Robertson)*, 112 U.S. 423 (1884), and a series of appellate court decisions decided under it, the courts have upheld charges as being fees—and not taxes—when the statute under which the charges were imposed was regulatory and the charges were closely tied to the regulatory purpose of the statute. *See, e.g., Brock* v. *Washington Metropolitan Area Transit Authority*, 796 F.2d 481 (D.C. Cir. 1986), *cert. denied*, 95 L.2d. 494, 107 S. Ct. 1887 (1987) and causes cited therein. The tests cited in these cases are discussed more fully below.

In *Federal Energy Administration* v. *Algonquin SNG, Inc.*, 426 U.S. 548 (1976) ("*FEA*"), the Supreme Court upheld a license fee imposed on imported goods under the Trade Expansion Act of 1962. The Court found that although this Act did not by its terms explicitly authorize the imposition of such license fees, it did include a grant of regulatory authority that was broad enough to encompass the charges. The Court further found that the legislative history of the Act contemplated license fees. Although not discussing any distinction between taxes and fees, the Court found that the statute provided sufficient guidance for agency action to avoid any question of "unconsitutional delegation of legislative power." *Id.* at 558–62.

2. Application to CFC Charges

EPA solicits comments on how to reconcile these various strands of the case law, and the extent to which the CFC charges would be permissible under the case law. The following is a brief sketch of some of the important issues.

The case law, particularly *NCTA* and appellate cases decided under it, may be read to indicate that the courts generally have been wary of upholding administrative charges, in particular charges that can be construed as representing "taxes," *i.e.*, of finding that Congress delegated to an agency the legislative authority under the Construction to impose taxes. See *e.g., National Association of Broadcasters* v. *Federal Communications Commission*, 554 F.2d 1118, 1129 n.28 (D.C. Cir. 1975). *But see* Gillete & Hopkins, *Federal User Fees: A Legal and Economic Analysis*, 67 B.U.L. Rev. 793, 822–24 (1987).

The argument that a CFC charge—either a fee or an auction—may be considered a "tax" under *NCTA* rests on the assertion that it is designed to serve public policy by eliminating the incentive to delay introducing chemical substitutes. If so, a CFC charge may not be authorized. On the other hand, it may be argued that the CFC charge amounts to a fee that is authorized because it is paid in exchange for the privilege granted by the Federal government to continue production of CFCs.

EPA is also soliciting comments on the extent to which the CFC charges meet the criteria in *Head Money Cases* and its progeny. In general, the administrative charges upheld under these cases involved (i) explicit statutory authorization for the charges and (ii) a close connection between the charges and the regulatory purpose of the statute, *e.g.*, in most of these cases, the funds were used by the agency as part of the regulatory scheme. *But see Rodgers* v. *United States*, 138 F.2d 992 (6th Cir. 1943). By contrast, the CFC charges—either a fee or an auction—are not explicitly authorized by statute and

[1] U.S. Constitution, Art. I, Sec. 8, cl. 1.

[2] U.S. Constitution, Art., I Sec. 8, cl. 3.

would not be used to fund the regulatory purpose of the statute.[3]

However, arguments may be made that the CFC charges are regulatory fees within the spirt of *Head Money Cases* and its progeny. The charges are designed to remove the economic incentive to delay the introduction of chemical substitutes that results from the sizable windfall profits that could accrue to the handful of CFC and halon producers by EPA's allocated quota regulation. As described above, if chemical substitutes are delayed, it may prove costly and difficult for industry to achieve the reductions required by the Montreal Protocol and by EPA's regulation. Moreover, any significant delay in the availability of new chemicals would make it more difficult to achieve greater or faster reductions in CFCs and halons if future changes in reduction occur. Seen in this light, according to this argument, the charges implement the regulatory purpose of CAA section 157(b), which is to protect the stratosphere. If chemical substitutes are not made available in a timely manner, the overall costs to society of meeting the regulatory goals would be increased as more expensive controls are used in lieu of chemical substitutes. As a result, it could be argued that the use of a charge as an adjunct to the allocated quotas system may be consistent with the provisions of section 157(b) that require the Agency to take into account the "feasibility and cost of achieving such control."

For much the same reasons, it may be argued that the charges implement the regulatory purposes of the TSCA. The legislative history of Section 6 of TSCA reveals specific congressional concern that certain steps be taken to minimize the chance that regulatory action might generate monopoly profits. *See* Conference Report on Toxic Substances Control Act, H. Rep. No. 94–1679, 94th Cong., 2d Sess. 75 (1976). However, as discussed below, it is uncertain whether this legislative history can be read to contemplate fees or auctions.

The case for CFC charges may also be strengthened by *FEA*, in which the Supreme Court upheld charges that were not explicitly authorized by statute in light of the broad scope of regulatory authority the statute granted. In that case, however, the Court further found that the legislative history of the statutory provision provides "much to suggest" that license fees were authorized. As discussed below, the legislative history of the Clean Air Act and TSCA is not as clearly favorable for CFC charges. Moreover, EPA is examining how to reconcile *FEA*—which did not raise the issue of whether the charges represented a delegation of the taxing power or the power to regulate commerce, and thus did not explicitly discuss whether the charges implement the regulatory purpose of the statute—with *Head Money Cases* and its progeny, which do not undertake that analysis.

EPA solicits comments on the extent to which the CAA or the TSCA, by its terms, provides sufficient guidance for imposing charges—either fees or auctions—to avoid delegation-of-legislative-power questions, under *FEA*.

B. Statutory Interpretation Issues

EPA is further examining the extent to which CFC charges fit within the intended scope of the regulatory authority Congress granted EPA under either CAA Sec. 157(b) or TSCA Sec. 6(a)(5). CAA Sec. 157(b), as quoted above, provides a grant of regulatory authority that is written broadly—"regulations for the control of any substance, practice, process, or activity * * * which * * * may reasonably be anticipated to affect the stratosphere * * *." Two commenters (public interest group, federal agency) argued that these terms are broad enough to permit the imposition of CFC charges. Further, the House Commerce Committee verified that Congress intended a broad grant of regulatory authority:

> Stratospheric protection measures are not confined to use of the best control technology or to requiring compliance with technologically feasible emission limitations * * * "[C]ontrols" may include design standards, work practice standards, prohibitions, and/or such other measures as may be necessary to assure protection for health and environment and to protect the stratosphere.

H. Rep. 94–1175, *reprinted in* "A Legislative History of the Clean Air Act Amendments of 1977" Congressional Research Service (1978) at 6630 n.2 ("Legislative History").

On the other hand, other aspects of the Clean Air Act Amendments of 1977 and the legislative history raise questions about the extent to which Congress believed that the concept of economic regulations was sufficiently well developed to be relied on. For example, Congress included in the CAA Amendments (i) section 120, which imposes a delayed compliance penalty on sources, and is computed by reference to the sources' pollution control costs saved as a result of the delayed compliance; and (ii) section 405(a), which directs a study on economic regulatory methods, including emission fees, by EPA and Council of Economic Advisors. Rep. Wirth, the author of this study provision, stated that the study provision has—

> great promise for improving our future efforts to control air pollution * * * [The provision] directs the Councils on Environmental Quality to study the effectiveness of using economic incentives to supplement our regulatory approach to pollution control. * * * [A]fter we look at the effect of [an early House version of the delayed compliance penalty provisions that would have determined the penalty by reference to amounts of emissions], and the results of the study * * * we should have enough evidence to adopt a comprehensive program of economic controls * * *[4]

These aspects of the legislative history may be interpreted to indicate that Congress, in adopting the CAA Amendments of 1977, did not believe that the concept of economic regulations, particularly emission fees, was sufficiently well developed at that time to be adopted.

However, EPA seeks comment on the extent to which Congress's concerns about economic controls primarily focused on using economic controls, in particular, emission fees, as the principal means of regulating pollutants that were already regulated under the 1970 Clean Air Act. Under this interpretation of the legislative history, Congress was primarily concerned about regulating pollution solely through emission fees; *i.e.*, allowing sources to emit as much pollution as they were willing to pay for. Under this interpretation, Congress was concerned that these types of emission fees (i) may not guarantee a particular level of pollution control (because, for example, if the fees were set too low, sources would emit more pollution than anticipated), (ii) could be administratively complex, and (iii) could have unforeseen economic effects on the industry.[5] It could be argued that at least some of these concern may not apply to CFC charges under either the fee system or the auction system described in this notice. For example, it could be argued that the CFC charges described in this notice would not jeopardize attainment of a particular level of pollution control because the amount of CFCs that may be produced

[3] Under 31 U.S.C. 3302(b), the funds collected through the CFC charges would go to the U.S. Treasury.

[4] Legislative History, at 6382.

[5] For example, Senator Muskie, one of the architects of the 1977 Clean Air Act Amendments, raised these concerns during a September 18, 1975 mark-up session held by the Subcommittee on Environmental Pollution, Committe on Public Works, concerning a proposal by Senator Buckley to impose an emission fee on emissions of sulfur dioxide.

and consumed would be limited separately. That is, CFC fees would simply supplement the allocated quota system. Similarly, an auction would simply be a method of distributing the allowable amount of CFC production and consumption rights.

TSCA Sec. 6(a)(5) is also written broadly—"prohibiting or otherwise regulating any manner or method of commercial use of such substance. . . ." EPA solicits comments on the extent to which these provisions may be broad enough by their terms to permit CFC charges. As discussed above, the legislative history of TSCA reveals specific congressional concern over monopoly profits that could result from EPA action to restrict supply of a substance. However, this legislative history seemed to result from earlier proposals to require EPA to impose specific allocations of quotas, under certain circumstances, if EPA limited production or use of a product. This legislative history does not explicitly authorize action, such as fees, to eliminate monopoly profits.

One commenter (federal agency) argued that EPA also had authority under the IOAA to impose CFC charges on the grounds that the IOAA authorizes fees in an amount up to the value of the benefit provided the recipient. This commenter stressed that in *NCTA*, the Supreme Court held that IOAA fees should be computed with reference to "value" granted by the agency to the recipient, and did not expressly limit the amount of fees to the agency costs in providing the benefit. The commenter acknowledged that at least four Federal Courts of Appeals, in at least eight decisions, following *NCTA* have stated that the IOAA limits fees to agency costs (or value provided the recipient, if lesser).[6] However, the commenter indicated that these statements were not relevant to the holdings of those cases. EPA invites further public comment on this issue, including on how clearly the appellate courts have spoken.

On a broader level, EPA seeks comments on whether interpreting the CAA, TSCA or the IOAA to permit EPA to charge CFC fees could result in interpreting these and perhaps other statutes to permit EPA and other agencies to impose other charges that could cumulate in substantial revenues. The potential significance of administrative agencies' collecting substantial revenues may be a factor in interpreting the statutes to allow this action.

C. Public Comment

The legal issues outlined above raise questions about the best way to proceed with the proposal for CFC charges. CFC charges will be more effective if imposed in the near future because even one or two years of windfall profits accruing to the current CFC producers could delay the introduction of substitutes, with detrimental results. If EPA imposed a fee in conjunction with allocated quotas, United States compliance with the Montreal Protocol would not be in jeopardy even if the regulatory fee were legally challenged. However, if EPA were to impose fees, a court were to invalide them, and Congress were then to impose them, the loss of time before the fees became effective could reduce their utility. Accordingly, EPA seeks comment on the overall extent of the legal risks noted above with respect to CFC fees, and the best course to follow in light of the risks.

Similarly, if a court invalidates the auction, the United States' compliance with the Montreal Protocol would be jeopardized. Thus, EPA seeks comment on the overall extent of the legal risks concerning an auction, and the best course to follow in light of the risks.

VI. Direct Controls on Use of CFC and Halons

In the December 14 proposed rule, the Agency described the possible need to develop a program of engineering controls or bans on CFC and halons, either alone or as a supplement to the allocated quotas, if users of these chemicals were postponing the adoption of technologically available, low-cost reductions. The central purpose of direct controls is to ensure that low-cost reductions would be made in a timely manner, thus preventing unwarranted price increases for the uncontrolled substances.

EPA received 48 comments addressing the issue of direct controls. Thirty commenters opposed the adoption of any technology-based controls or bans. Generally, these comments cited as the major disadvantages of direct controls, the elimination of incentives to develop substitutes and innovative practices, the likelihood of high administrative and compliance costs, the uncertain level of environmental protection, and economic inefficiency as a result of inflexibility and unresponsiveness to changing technological innovations and economic conditions.

In contrast, eighteen commenters favored engineering controls and bans for some CFC and halon applications, because they believe that despite CFC price increases, voluntary and timely reductions by industry are unlikely in the near term. Seven commenters preferred that industry-specific engineering controls or bans be imposed in conjunction with allocated quotas. One commenter believed that such a "hybrid" would protect foam-blowing applications, an end use where near-term substitutes may not be readily available, from having to bear excesssive CFC price increases.

For many of the reasons outlined in these comments, EPA did not promulgate direct controls in the final rule published elsewhere in today's **Federal Register**. However, the Agency believes that direct controls, when used in conjunction with the allocated quota system, under certain conditions (e.g., to overcome market imperfections) offer a potential cost-saving to allocated quotas.

While the allocated quota system, by itself, requires that the Protocol's mandated reductions in CFCs and halons occur and thus fully implements the requirements of the Montreal Protocol, the addition of a program of direct controls would ensure that low-cost reductions are adopted.

Potential disadvantages of direct regulations, such as high compliance and administrative costs, depend on the type of controls adopted. For example, a ban of CFCs in some end use applications would be simple to administer and enforce. EPA also believes that innovative technologies would develop if prospective bans were imposed in conjunction with allocated quotas and that it is possible to design such regulations for select user groups that would minimize the disadvantages of this traditional regulatory approach. Several other nations (e.g., Canada, Japan, and Sweden) are considering this form of hybrid approach for their implementation of the Montreal Protocol.

A. Need for Direct Controls

As part of its revised RIA, EPA examined the potential impact of delayed efforts by user industries to adopt low-cost reduction technologies in a timely manner. This analysis compared two scenarios. The Case 1 scenario assumed key user industries

[6] The commentator cited the following decisions: *Central & Southern Motor Freight Tariff Ass'n* v. *United States*, 777 F.2d 722, 729 (D.C. Cir. 1985); *Nevada Power Co.* v. *Watt*, 711 F.2d 913, 933 (10th Cir. 1983); *Yosemite Park and Curry Co.* v. *United States*, 686 F.2d 925, 931 (Ct. Cl.1982); *Mississippi Power & Light* v. *NRC*, 601 F.2d 223, 230 (5th Cir. 1979), *cert. denied*, 444 U.S. 1102 (1980); *National Cable Television Ass'n* v. *United States*, 554 F.2d 1094, 1106–07 (D.C. Cir. 1976); *Electronic Industries Ass'n* v. *FCC*, 554 F.2d 1109, 1114–15 (D.C. Cir. 1976); *National Ass'n of Broadcasters* v. *FCC*, 554 F.2d 1118, 1128 (D.C. Cir. 1976); *Capital Cities Communications, Inc.* v. *FCC*, 554 F.2d 1135, 1138 (D.C. Cir 1976).

delayed the date at which they began shifting away from CFCs and that a lower percentage of firms in a user industry made the shift over a longer period of time. The Case 2 scenario assumes exactly the opposite; firms aggressively move away from CFCs to alternative technologies and increased recycling and recovery. Tables 2 and 3 show the user industries examined in this analysis and the assumptions used in the Case 1 and 2 scenarios, respectively. These assumptions were entered into the Integrated Assessment Model (IAM) used in the RIA. This model determines likely CFC price effects based on assumptions concerning control options and actions by industries.

TABLE 2.—CASE 1 ASSUMPTIONS ABOUT TECHNICAL FEASIBILITY OF CFC-CONSERVING TECHNOLOGIES

Sector/technology	Start date [a]	Penetration time [b]	Use-specific reduction potential in 1988 [c]
Mobile Air Conditioning:			
Recovery at Service-Large Shops	1989	3	6.5%
Recovery at Service-Medium Shops	([d])	([d])	([d])
Recovery at Service-Small Shops	([d])	([d])	([d])
DME	([d])	([d])	([d])
Solvents:			
Terpenes and Aqueous Cleaning	1988	5	24%
CFC-113 Azeotropes	1989	4	[e] 7%
Housekeeping	1989	1	[f] 5-12%
HCFC-123	([d])	([d])	([d])
Hospital Sterilization:			
Disposables	1988	9	22%
Alternate Blends	1988	5	7%
Contracting Out	1988	9	4%
Steam Cleaning	([d])	([d])	([d])
Refrigeration:			
Recovery at Service	1988	5	3-11%
Recovery at Rework	1988	3	2%
FC-134a	1992	[f] 10-21	[f] 5-53%
Foam Insulation:			
Product Substitutes	1990	[f] 5-10	[f] 20-40%
HCFC-123	1992	3	[f] 27-50%
HCFC-141b	1991	3	[f] 30-50%
Flexible Foam-Molded:			
Water-Blown Processes	1988	3	41%
HCFC-141b	1991	9	18%
Flexible Foam-Slabstock:			
HCFC-123	1992	9	26%
HCFC-141b	1991	9	18%
Foam Packaging:			
Product Substitutes	1988	[f] 3-5	[f] 10-51%
HCFC-22	1988	2	[f] 0-90%
Aerosols:			
Carbon Dioxide	1988	4	25%

TABLE 2.—CASE 1 ASSUMPTIONS ABOUT TECHNICAL FEASIBILITY OF CFC-CONSERVING TECHNOLOGIES—Continued

Sector/technology	Start date [a]	Penetration time [b]	Use-specific reduction potential in 1988 [c]
HCFC-22 Blends	1988	2	25%

NOTES:
[a] Year in which technology initially becomes available for commercial use.
[b] Years until maximum use of technology is achieved.
[c] Possible reduction in CFC use for the sector in 1998 for this control only. Some technologies can only control a small percentage of an application's use. Thus, a number smaller than 100% may not indicate low penetration but may indicate that the control can only eliminate a small percentage of the application's use.
[d] Case 1 assumes that no CFC reductions are possible through this technology.
[e] Azeotrope consists of 70 percent CFC-113. The reduction shown reflects the 30 percent reduction in CFC-113 achieved when using the azeotrope and the fraction of the solvent sector adopting the azeotropes.
[f] Ranges reflect differences in assumptions about technical feasibility of adopting technology by subsectors within this sector (e.g., in some subsectors the reductions are lower than others). Within particular subsectors, the reductions do not exceed 100 percent.

TABLE 3.—CASE 2 ASSUMPTIONS ABOUT TECHNICAL FEASIBILITY OF CFC-CONSERVING TECHNOLOGIES

Sector/technology	Start date [a]	Penetration time [b]	Use-specific reduction potential in 1988 [c]
Mobile Air Conditioning:			
Recovery at Service-Large Shops	1989	3	6.5%
Recovery at Service-Medium Shops	1989	3	19.2%
Recovery at Service-Small Shops	1989	3	7%
DME	1989	3	20%
Solvents:			
Terpenes and Aqueous Cleaning	1988	5	50%
CFC-113 Azeotropes	1989	4	12% [d]
Housekeeping	1989	1	14%
HCFC-123	1992	10	3%
Hospital Sterilization:			
Disposables	1988	5	35%
Alternate Blends	1988	3	35%
Contracting Out	1988	9	5%
Steam Cleaning	1988	1	10%
Refrigeration:			
Recovery at Service	1988	4-9 [e]	6-27% [e]
Recovery at Rework	1988	2	2%
FC-134a	1992	10-21 [e]	50-100% [e]
Foam Insulation:			
Product Substitutes	1990	5	10-80% [e]
HCFC-123	1992	3	17-50% [e]
HCFC-141b	1991	3	20-50% [e]

TABLE 3.—CASE 2 ASSUMPTIONS ABOUT TECHNICAL FEASIBILITY OF CFC-CONSERVING TECHNOLOGIES—Continued

Sector/technology	Start date [a]	Penetration time [b]	Use-specific reduction potential in 1988 [c]
Flexible Form-Molded:			
Water-Blown Processes	1988	1	63%
HCFC-14b	1991	9	36%
Flexible Foam-Slabstock:			
HCFC-123	1992	9	24%
HCFC-141b	1991	9	40%
Foam Packaging:			
Product Substitutes	1988	3-5 [e]	20-60% [e]
HCFC-22	1988	2	0-96%
Aerosols:			
Carbon Dioxide	1988	4	50%
HCFC-22 Blends	1988	4	50%

NOTES: [a] Year in which technology initially becomes available for commercial use.
[b] Years until maximum use of technology is achieved.
[c] Possible reduction potential for response action in 1998 for this control only. Some technologies can only control a small percentage of an applications use. Thus a number smaller than 100% may not indicate low penetration but may indicate that the control can only eliminate a small percentage of the applications use.
[d] Azeotrope consists of 70 percent CFC-113. The reduction shown reflects the 30 percent reduction in CFC-113 achieved when using the azeotrope and the fraction of the solvent sector adopting the azeotropes.
[e] Ranges reflect differences in assumptions about technical feasibility of adopting technology by subsectors within this subsector (e.g., in some subsectors the reductions are lower than others). Within particular subsectors, the reductions do not exceed 100 percent.

Table 1 presented earlier shows the economic impact of delays in implementing low-cost reduction technologies. It shows that substantial increases in total costs (from just over $1 billion in Case 2 to almost $3 billion in Case 1 through the turn of the century) would result. It also shows that windfall profits (pre-tax) through the year 2000 would as much as triple, going from just under $2 billion in Case 2 to over $7 billion in Case 1. CFC prices would shift from no increase in the initial years under the Case 2 scenario to price increases of $5-6.00/kg in the early years under the Case 1 scenario.

Based on this analysis, it appears that control actions in the next few years will have a substantial impact on short-term costs of reducing use of CFCs and halons, but far less impact on longer-term costs. However, short-term price effects are critical to encouraging an orderly transition away from these chemicals with minimum disruption to the nation's economy, and in avoiding adverse environmental consequences discussed above.

The extent to which near-term price increases can be minimized is also

crucial to the ability of potentially vulnerable industrial users of CFCs (e.g., certain foam applications) to maintain their markets prior to the availability of chemical substitutes. If these firms are not confronted with steep near-term price increases, they will be better able to continue manufacturing until chemical substances become available.

B. Criteria for Selecting Direct Controls

The December 14 proposal outlined several criteria EPA may use to develop possible controls. First, the Agency would review low-cost reductions currently available within each user group. It is these reductions that EPA believes that industry will or should undertake during the initial years of the allocated quota system. For some end use applications, low-cost options may not currently be available; for others, control options are currently available but may not be implemented due to the small cost of CFCs relative to the total cost of the product or due to the ability to pass higher costs on to consumers. EPA intends to closely monitor the pace at which reductions are being made and if necessary develop control requirements. EPA is requesting comment on the level of reduction in CFC and halon use or rate of progress toward substitutes which EPA should expect within these industries to indicate each industry's commitment to reduction in use of these chemicals.

Second, the Agency will be concerned with the administrative burden associated with monitoring compliance and enforcing its regulations. EPA may target end use applications where volumes of CFCs and halons consumed are easily monitored or where uses can be banned, rather than mandating tecnology-based controls which generally require extensive compliance with monitoring and site inspections by EPA inspectors.

Finally, EPA will avoid, if possible, direct regulations on small businesses. The Agency believes that the small business community should not bear an inordinate burden relative to larger businesses to comply with the stratospheric ozone program. Furthermore, it is much more likely that small business will undertake measures to reduce their use of controlled substances since they will be unable to absorb large increases in the price of CFCs and halons. The large number of small businesses potentially regulated also presents compliance monitoring and enforcement problems.

EPA will closely monitor industry responses to today's final rule and review the development of reductions in CFC and halon uses over the coming years. EPA believes that if reductions do occur then subsequent price increases of controlled substances will be moderate. If available reductions are not adopted, however, and prices increase significantly, this would signal the need for direct controls on user applications. EPA is also seeking public comment on the possible role of voluntary, as opposed to mandatory controls, and the potential to use some form of negotiated rulemaking process with specific user groups.

C. Potential Near-Term User Regulations

Based on the analysis contained in its RIA and the criteria described above, EPA has identified several industry sectors where direct regulation in the near term may be appropriate. To understand the impact of controls implemented within individual sectors, EPA estimated, through the IAM model, price increases of controlled chemicals when an individual sector alone adopts low-cost controls. In some instances, sectors which use a relatively small percentage of the total of controlled substances can prevent large price increases if controls can either substantially eliminate CFC use in the sector or can be used by a high percentage of firms in that sector. In contrast, CFC price impacts from controls in a larger CFC user sector may not be as great due to limited market penetration.

1. Automobile Air Conditioning

Approximately 25 percent of all domestically-consumed CFCs are currently used in auto air conditioners, making it the single largest use of these chemicals. Moreover, current servicing practices result in substantial unnecessary emissions of CFC–12. Typically, any CFC–12 remaining in the auto air conditioner is first vented to the air, a new charge of CFC–12 is sometimes used to test the system and to locate the leak, and finally the system is recharged. Additional waste may occur when "do-it-yourselfers" either charge systems repeatedly what repairing the levels, overcharge systems, or discharge unused chemical from the small cans used to recharge systems.

Several groups (automobile manufacturers, servicing trade associations and recycling equipment manufacturers) are not working together to develop a standard for recycling CFC–12 for car air conditioners. If this step alone were taken, the resulting reductions in CFC demand would reduce the price of CFCs in 1989 from $6.69/kg in the Case 1 scenario to $4.49/kg. Because of the importance of this step, EPA intends to closely monitor progress toward recycling by this industry segment and intends to develop mandatory regulations requiring recycling in all service shops by 1992 if near-term progress toward the use of recycling in this industry segment does not occur.

In addition, DME/12 blend, a mixture of CFC–12 and dimethylether, is a potential "drop-in" replacement for CFC–12, and has considerably lower ozone-depleting potential than CFC–12. Assuming the additional tests of this blend that are underway prove that it can safely be used in existing auto air conditioning systems, EPA believes that automobile manufacturers and service repairmen could replace CFC–12 with the DME/12 blend during initial charging and future servicing. EPA estimates that the DME/12 blend could replace 20 to 30 percent of CFC–12 used in these applications if such a practice is accepted under the automobile warranties which currently require pure CFC–12 as the replacement refrigerant. If adopted, DME/12 blend could reduce price increases from $6.69 per kilogram in Case 1 to $2.21 per kilogram.

2. Hospital Sterilization

Hospital sterilization accounts for 4 percent of all CFCs used within the United States. Although this application consumes a small percentage relative to other uses, there are several immediate opportunities to decrease its use of CFC–12. To minimize CFC price increases, hospitals could expand their use of disposable medical items, potentially displacing 45 percent of CFC–12 used for sterilization. Hospitals could also contract to have sterilization done by external facilities which would use less CFC–12 in total than individual hospitals, saving approximately 5 percent of CFC–12 currently used in this application. Finally, alternate blends of chemicals and steam cleaning could together displace an additional 45 percent of CFC–12 used within this application.

There are several obstacles to the adoption of these technologies. Acceptance by hospital administrators, physicians and staff who may be biased toward more traditional means of sterilization is crucial. Further development of off-site sterilization facilities and disposable instruments are also necessary. Finally, any new sterilants must be submitted to and approved by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act. If these alternatives were available and implemented in 1988, price increases could be reduced from $6.69

per kilogram to $2.21 per kilogram in 1989. Due to this potential saving for a relatively small user groups, EPA intends to monitor this user industry and require a ban of CFC-12 use in hospital sterilization if expected reductions do not occur.

3. Aerosols

Current uses of CFCs in aerosols were exempted from the 1978 aerosol ban and account for approximately five percent of the total CFC usage in the United States. Several alternative aerosol propellants and alternative delivery systems have been developed since the original aerosol exemptions were granted. A complete ban of CFCs within aerosols would reduce the price increase in 1989 from $6.69 per kilogram in Case 1 to $2.79 per kilogram. EPA may propose product labeling and further restrictions on aerosol use.

4. Solvents

Approximately 12 percent of all domestically consumed CFCs are used in solvent cleaning of metal and electronic parts. This area also has several potential alternatives or process modifications to minimize the use and thus the demand for CFC-113. The use of terpene and aqueous cleaning as substitutes for CFC-113 based solvents can provide approximately a 50 percent reduction in CFC-113 within this application by 1998. The timely application of CFC-113 azeotropes or mixtures and improved housekeeping practices to minimize vent losses or spills could further reduce CFC demand by an additional 20 percent. If all controls are adopted, the expected price rise is only $1.95 per kilogram, rather than $6.69 under the "Case 1" scenario. EPA recognizes however that solvent applications are difficult to characterize and that not all uses could shift to the suggested alternatives. While several large firms have recently made substantial strides toward reducing their reliance on CFCs, EPA will closely monitor this industry to determine if direct regulations are required and to better define which applications should be controlled.

D. Potential Long-Term Reductions and Controls

1. Commercial Air Conditioning

The December 14 proposal described several trends within the commercial air conditioning sector away from the controlled substances. Commercial chillers have already begun to shift to HCFC-22, CFC-502 and CFC-500, which are chemicals and mixes with ozone depletion weights that are significantly lower than CFC-11 and CFC-12. CFC recovery during routine maintenance would further reduce CFC emissions. Recovery of refrigerant during maintenance is not currently standard industry practice. Regulations requiring recovery may be necessary to ensure low cost reductions are made as CFC prices increase. For the future, alternative chemicals such as HCFC-134a, HCFC-123, DME/CFC-12 or HCFC-22/142b may replace CFC-11 and CFC-12 in new equipment.

2. Automobile Air Conditioning

Over the long term, EPA believes that the automobile manufacturers will have several chemical substitutes available. One promising alternative is HFC-134a, a chemical that the major automobile manufacturers, in their comments, pointed to as the most likely substitute, but one that will require several years to develop, test and begin integrating into the automobile fleet. However, other chemicals are also under active consideration worldwide. Finally, as discussed above, a blend of dimethylether and CFC-12 may be another possible alternative to pure CFC-12 refrigerant in existing and new equipment.

Although future automobile air conditioners may contain HFC-134a or some other refrigerant, the existing fleet of automobiles will continue to consume CFC-12. Venting during repair and losses due to refrigerant trapped within discarded containers contribute to large emissions of CFCs when eventually released. As mentioned earlier, EPA is investigating the possibility of requiring recycling at time of servicing and the use of a DME/CFC-12 blend as replacement coolant.

3. Electronics and Metal Cleaning

The electronic industry uses CFC-113 as a solvent; its use has grown substantially over the past years due to health concerns about alternative chlorinated solvents. The December 14 proposal noted that the high cost of CFC-113 and the fact that it is recoverable makes it economically attractive to recover and recycle CFC-113. For the same reason, EPA believes recovery and recycling are possible candidates for mandated controls. Existing equipment frequently does not have automatic covers or hoists (in the case of open top vapor degreasers) to reduce losses. Better operating practices or "housekeeping" could further reduce CFC losses. As mentioned above, alternatives such as aqueous cleaners or terpenes, are likely to play a large role in reducing this user group's dependence on CFC-113 and other chlorinated solvents. EPA expressly does not view shifting from CFC-113 to other chlorinated solvents which are currently under regulatory scrutiny as an acceptable solution to protecting the ozone layer.

Several commenters questioned EPA's previous estimates that aqueous cleaning would replace a large share of CFC-113 use. EPA does estimate that 50 percent of CFC-113 will be replaced by both aqueous and terpene-based solutions. Commenters believed that the diversity of the electronics manufacturing industry makes it necessary to examine the suitability of these substitutes on a case-by-case basis and that across the board recommendations or controls are not possible.

EPA recognizes the diverse nature of the electronics industry and will account for this diversity should direct controls be considered.

4. Flexible Foam

EPA discussed in the December 14 proposal possible controls applicable to the flexible foam industry, including makers of polyurethane foam slabstock. CFC-11 is an auxiliary blowing agent used by slabstock makers who manufacture cushions, mattresses and bedding. At this time, no chemical substitutes are currently available, but EPA believes that flexible foam-blowers may manufacture slabstock without CFCs. The elimination of the auxiliary blowing agent would result in firmer, higher density foam cushions for automobile seats. Over the longer term, modified polyols may be used to decrease foam densitiy to provide a softer foam simlar to CFC-11 blown foam. In addition, foam-blowers may increase water content of the foam to reduce density. In the long term, HCFC-123 or another chemical substitute may become a viable replacement for CFC-11 in many foam applications.

In response to EPA's discussion in the proposal, several automobile manufacturers indicated that efforts to replace CFC-11 in molded flexible foam seats for automobiles have been fairly successful, and that water-blown technologies can create the proper foam densities. Given the success with automobile cushioned seats, a ban of CFC-11 within this application may be appropriate.

5. Commercial and Residential Refrigeration

Like commercial air conditioning, commercial refrigeration is shifting toward other less ozone-depleting chemicals such as HCFC-22, CFC-502

and CFC-500. Manufacturers can also reduce emissions through alternate leak testing and recovery of CFC-12 during rework of the unit during test runs in the factory. Over the long term, HFC-134a or some other chemical substitute may replace CFC-12 in new equipment. A wide range of alternative refrigerants are also being explored for residential refrigerators.

Twenty commenters claimed that there were no currently available alternatives to CFC-11, 12 and 502. Industry also believes that the adoption of HFC-134a as a future alternative chemical will require large capital costs as factories retool to produce new refrigeration units. EPA is currently reviewing the possibility of HCFC-22, dimethylether/CFC-12, and HCFC-22/142b as substitutes for these end use applications. In the near term, increased use of recovery and recycling of refrigerant during servicing and use of DME/12 blend may be the most attractive options. Over the longer term, new refrigerants which reduce dependence on CFCs without sacrificing energy efficiency will represent the most acceptable market solutions.

6. Rigid Insulating Foams

CFC-11 is used as a blowing agent to make various forms of insulating foams such as polyurethane, isocyanurate, and phenolic foams. In the short term, HCFC-22 can be used in polystyrene insulation, and blends may be developed which reduce use of CFC-11, but there are no commonly accepted chemical substitutes for other rigid foams. There are possibilities that product substitutes may attract part of the insulation market from this end use application. Over the long term, HCFC-123 or HCFC-141b may become an attractive means of reducing this use of CFC-11.

7. Rigid Packaging Foams

Polystyrene foam is widely used in the food packaging industry. CFC-12 is primarily used as a blowing agent and currently competes with pentane. In contrast to pentane, which is flammable and contributes to air pollution, HCFC-22 may be a more suitable substitute for CFC-12. The Food and Drug Administration has recently approved the use of HCFC-22 in food service applications. The most comprehensive data on HCFC-22 for polystyrene foam suggests that firms will incur only limited capital costs and that operating costs are not expected to increase with the adoption of HCFC-22. In response to the development of this alternative, the industry has proposed to phase-out voluntarily the use of CFC-12 in food packaging by December 31, 1988.

8. Total Flooding Fire Extinguishant Systems

Halon 1301 is used as the agent in total flooding fire extinguishant systems to protect computer centers, document rooms, libraries, military installation, etc. Due to its unique features (non-toxic, non-residue forming), there are currently no available substitutes.

EPA believes that in the short term voluntary reduction will occur within the industry to reduce unnecessary emissions. Discharge testing of new systems using halons is being reduced or even eliminated as alternative test gases are being developed and employed. EPA's analysis of halon emission patterns indicate that only approximately 25 percent of all halon emissions are emitted to fight an actual fire. All other emissions are a result of accidental discharges, training procedures, and system and discharge testing.

Research efforts must focus on better ways to design systems which require less agent for the required protection, on appropriate methods for determining when halon protection is in fact necessary, and on the development of chemical substitutes.

9. Halon Fire Extinguishers

Halon 1211 is used extensively in portable fire extinguishers in markets where concerns exist about human exposure to and harm from residues from other agents. In addition to this market, portable fire extinguishers have penetrated consumer markets and some percentage are now purchased and used for applications where other fire extinguishing agents would be suitable.

EPA is currently considering restricting the sale of portable halon extinguishers for home use. Small halon extinguishers are relatively inexpensive and are purchased even where other agents might be used. Mandated controls could limit the sale of extinguishers in markets where substitutes are readily available.

10. Sterilization

The December 14 proposal outlined several available ways of reducing the use of CFC-12 to sterilize medical equipment. These options include the use of mixtures of carbon dioxide and ethylene oxide, cobalt radiation, and recovery of CFC-12 with carbon adsorption and refrigerated condensers. Several commenters on the December 14 proposal disagreed that these options are available, stating that no widely available means of reducing CFC-12 use are as safe or effective as the ethylene oxide and CFC-12 mixture.

EPA continues to believe that the options are commercially available and have been successfully demonstrated in the United States. Two of the methods, cobalt and gamma irradiation of equipment, have proven successful and indicate potential for future growth. The carbon dioxide and ethylene oxide mixture may require chamber replacement, and pure ethylene oxide for sterilization will require an explosion proof chamber, but over a long time period it may be cost-effective for commercial sterilizers and large hospitals to switch to these alternatives. For these reasons, EPA believes that sterilization end use application may be a likely candidate for direct controls.

E. Barriers to Reducing CFC and Halon Use

EPA is also seeking public comment on specific institutional barriers to reducing the use of CFCs and halons. Several commenters expressed concerns that such factors as energy efficiency standards, purchasing specifications, conflicting environmental laws and regulations, states and local codes, industry warranties, etc., may impede progress in moving away from ozone-depleting chemicals.

EPA has initiated or is participating in studies in several of these areas to determine what steps are necessary to reconcile potentially conflicting goals and to remove needless institutional barriers. EPA welcomes additional comment on relevant aspects of this issue.

F. Labelling

In addition to the allocated quota system, auctions, and direct controls for specified user industries, EPA is also considering labelling requirements for products containing or manufactured with CFCs. As discussed in the December 14 proposal, EPA believes labelling provides useful information to consumers, increasing their awareness of the ozone issue and allowing the public to make informed decisions on purchases. In turn, a change in demand will assist the industry in moving toward alternatives. Indeed, EPA believes labelling was an effective impetus in moving industry away from CFC use before the 1978 aerosol ban and has been proposed by several other nations (e.g. Canada and European Economic Community) as part of their plans to implement the Montreal Protocol.

Ten commenters believed that labelling could be an important part of

the final EPA regulation, providing consumers with information that will allow them to make choices which protect the ozone layer, helping to prevent the misuse of CFC and halon products, and providing a marketplace incentive for manufacturers either to implement promptly a substitute for CFCs or to alter their products to eliminate CFCs.

Seventy-four commenters opposed a labelling requirement, believing that labelling would adversely affect their business. Commenters stated that labelling could cause consumer panic and affect industry's research and development efforts. User groups believe that labelling will drive up the cost of products, and adversely affect firms where chemical substitutes are not available.

Currently, EPA has not fully investigated the potential costs and benefits of labelling in either general or specific applications of the requirement. EPA intends to further investigate the need for and potential role of labelling and requests additional comments on this possible future requirement.

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Date: August 1, 1988.

Lee M. Thomas,

Administrator.

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Part V

Department of the Interior

Fish and Wildlife Service

50 CFR Part 20

Migratory Bird Hunting; Proposed Frameworks for Late Season Migratory Bird Hunting Regulations; Supplemental Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

Migratory Bird Hunting; Proposed Frameworks for Late Season Migratory Bird Hunting Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Supplemental proposed rule.

SUMMARY: This document supplements proposed rulemakings published in the **Federal Register** on March 9 and June 7, 1988 (53 FR 7702 and 53 FR 20874) and sets forth proposed frameworks (i.e., the outer limits for dates and times when shooting may occur, hunting areas, and the number of birds which may be taken and possessed) for late-season migratory bird hunting regulations for 1988–89. These seasons generally will commence on or about October 1, 1988, and include most of those for waterfowl.

The Service annually prescribes migratory bird hunting regulations frameworks to the States. The effect of this proposed rule is to facilitate the selection of hunting seasons by the States and to further the establishment of the late-season migratory bird hunting regulations for 1988–89. These proposed frameworks differ substantially from last year. The section on Supplementary Information includes a statement by the Director of the U.S. Fish and Wildlife Service and information on the status of ducks which explain the reasons for proposed changes.

DATE: The comment period for these proposed late-season frameworks will end on August 25, 1988.

ADDRESS COMMENTS TO: Director (FWS/MBMO), U.S. Fish and Wildlife Service, Department of the Interior, Matomic Building, Room 536, Washington, DC 20240. Comments received on these proposed late-season frameworks will be available for public inspection during normal business hours in Room 536, Matomic Building, 1717 H Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Rollin D. Sparrowe, Chief, Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240 (202–254–3207).

SUPPLEMENTARY INFORMATION: The Migratory Bird Treaty Act of July 3, 1918 (40 Stat. 755; 16 U.S.C. 703 et seq.), as amended, authorizes and directs the Secretary of the Interior, having due regard for the zones of temperature and for the distribution, abundance, economic value, breeding habits, and times and lines of flight of migratory game birds to determine when, to what extent and by what means such birds or any part, nest or egg thereof may be taken, hunted, captured, killed, possessed, sold, purchased, shipped, carried, exported or transported.

On March 9, 1988, the U.S. Fish and Wildlife Service (hereinafter the Service) published for public comment in the **Federal Register** (53 FR 7702) a proposal to amend 50 CFR Part 20, with comment periods ending June 22, 1988, for Alaska, Hawaii, Puerto Rico, and the Virgin Islands; July 18, 1988, for other early-season proposals; and August 29, 1988, for the late-season proposals. The March 9 document dealt with the establishment of hunting seasons, hours, areas and limits for migratory game birds under §§ 20.101 through 20.107, 20.109 and 20.110 of Subpart K. On June 7, 1988, the Service published in the **Federal Register** (53 FR 20874) a second document consisting of a supplemental proposed rulemaking dealing with both the early- and late-season frameworks. On July 11, 1988, the Service published for public comment in the **Federal Register** (53 FR 26198) a third document consisting of a proposed rulemaking dealing specifically with frameworks for early-season migratory bird hunting regulations. That document also reopened and extended the comment period for the proposed frameworks for Alaska, Puerto Rico and Virgin Islands from June 22, 1988, to July 20, 1988. All three documents, March 9, June 7, and July 11, indicated that special consideration was being given to possible restrictive regulations for all aspects of the 1988–89 hunting season dependent upon the continuing poor status of ducks. On August 9, 1988, the Service published a fourth document (53 FR 29897) containing final frameworks for early migratory bird hunting seasons from which wildlife conservation agency officials from the States, Puerto Rico and the Virgin Islands selected early-season hunting dates, hours, areas and limits for 1988–89. This document is the fifth in the series and deals specifically with proposed frameworks for the 1988–89 late-season migratory bird hunting regulations. Before September 1, 1988, the Service intends to publish in the **Federal Register** a sixth document consisting of a final rule amending Subpart K of 50 CFR 20 to set hunting seasons, hours, areas and limits for mourning doves, white-winged and white-tipped doves, bank-tailed pigeons, rails, woodcock, snipe, common moorhens and purple gallinules; sea duck seasons in certain defined areas of the Atlantic Flyway; experimental September duck seasons in three States; experimental September Canada goose seasons in three States; sandhill cranes; a special Canada goose season in southwestern Wyoming; migratory game birds in Alaska, Hawaii, Puerto Rico, and the Virgin Islands; and extended falconry seasons.

Statement by Frank Dunkle, Director, U.S. Fish and Wildlife Service

The U.S. Fish and Wildlife Service is responsible for this Nation's migratory waterfowl resources. Each year, the agency adopts regulations governing the hunting of migratory waterfowl. It sets restrictions on the number of days hunters can hunt, a framework of dates for when the season can open or close, and bag limits on the number and kind of ducks or geese that can be taken.

This has been a terrible year for ducks. The continuing drought in many prime waterfowl breeding areas of Canada and the northcentral United States severely limited their ability to nest. Since last year, more than 1 million small wetlands have dried up. Service biologists are projecting a fall flight index of 66 million ducks—the second lowest on record. This is down from 1987's fall flight of 74 million birds.

During the period 1985–87, restrictions on hunting reduced duck harvest by 25 percent. This year's down-turn in duck numbers indicates the need for further restrictions.

In light of the current situation, I am recommending the following restrictions to further reduce harvest during the 1988 waterfowl hunting season:

- Reducing hunting days in all flyways by 25 percent;
- Shortening duck season opening and closing dates to October 8–January 8 in all flyways;
- Reducing bag limits by one duck in all flyways;
- Suspending special scaup seasons and bonus scaup and teal limits;
- Suspending the point system in determining bag limits for this year in all flyways. This is to be followed by a thorough review of this system prior to setting regulations for the 1989–90 hunting season;
- Closing the season on canvasback ducks in all flyways;
- Severely limiting pintail seasons in all flyways;
- Reducing mallard bag limits; and
- Suspending half-hour before sunrise shooting hours for this year. Sunrise will be the official starting time for shooting in 1988–89, and will be followed by a review of this issue prior to setting regulations for the 1989–90 hunting season. This will further reduce harvest and assist hunters in accurately distinguishing different species of ducks in flight. To achieve the necessary harvest reductions without this suspension would require more severe restrictions in other areas, for example, a further reduced bag, a further reduction in hunting days, and/or other more restrictive measures.

I am confident these restrictions will result in at least a 25 percent reduction in duck harvest from the average achieved during the 1985–87 period. I believe a reduction of this

magnitude is necessary to protect duck broodstocks during this drought.

In addition, the Service will monitor waterfowl migration and wintering areas this season. If the drought results in unusual concentrations of birds, making them vulnerable to hunters, I will not hesitate to utilize my authority to close the season in some areas.

Our current waterfowl situation underscores the importance of the North American Waterfowl Management Plan. This international agreement, signed by representatives of the United States and Canada, is aimed at preservation and enhancement of sufficient wetlands and other habitats on this continent to support fall flights of 100 million ducks. A parallel agreement with Mexico is expanding this important work into that country. Hunting is not the cause of the current decline in duck numbers. It is, however, one influence that must be regulated when populations are low. The long-term health of waterfowl depends on our ability to protect and enhance the wetland habitat which sustain these creatures.

Numerous waterfowlers have told me they plan to cut back voluntarily on the number of ducks they take this season, or even not hunt at all. I support these grass-roots conservation efforts, but urge those who choose not to hunt to at least purchase a Duck Stamp and help provide dollars that are vital to out habitat acquisition efforts.

While these changes in the waterfowl regulations may seem drastic, bold action is called for. I am confident this Nation's waterfowlers will understand the necessity of taking these steps and will make the sacrifices necessary to insure the future integrity of waterfowl populations, wetland habitats, and the sport of waterfowling.

Frank Dunkle,

Director.

Review of 1980–88 Duck Situation

The decade of the 1980's has not been good for ducks and their habitat across large areas of North America. Continued widespread drought, and agricultural impacts on wetlands in Canada and the north-central United States led to record-low duck breeding populations, and the lowest fall flight on record in 1985. Restrictive hunting regulations during 1985–87, in combination with low numbers of ducks, reduced harvest by 25 percent, with nearly equal reductions in each of the four flyways. Harvest rates on mallards were reduced significantly for all sex and age classes. Since then the drought has intensified and habitat destruction has continued, which has slowed recovery of duck breeding populations. The disastrous drought of 1988 has reduced populations again almost to the levels of 1985. The problem is not one of a single year of severe drought in 1988, but the result of several years of repeated poor conditions. Some important breeding areas in Prairie Canada have been extremely dry since 1980, while others have experienced wet and dry cycles, but nearly all are dry in 1988. The period of the 1980's has seen three of the five lowest May pond counts on record in Prairie Canada. This year, severe drought also may adversely affect migration and wintering areas. Low stream flows, grain-crop failures, less natural food, and water shortages likely will tend to concentrate waterfowl, especially at critical migration stopovers and wintering sites. Such concentrations can lead to disease problems and greater vulnerability to hunting in addition to sending birds back to the breeding grounds in poor condition next spring.

Agricultural impact on marshes and surrounding habitats in Prairie Canada has accelerated because of the drought and has seriously reduced the capability of traditional Canadian prairie habitats to produce ducks. Several years of good climatic conditions will be required before many drought-stricken areas can recover, revegetate, and produce ducks again. However, because of the widespread destruction of natural wetlands and the conversion of potential nesting areas of agriculture, many areas once important to breeding ducks have been permanently affected. This factor will influence decisions about waterfowl harvest management for more than a single year. Breeding populations and production are showing the effects of both short and long-term stress on primary habitats.

May surveys indicates that ducks were displaced from their traditional prairie habitats more during 1988 than in any year of record. Extremely high numbers of mallards, pintails, and blue-winged teal were displaced to the far north into habitats which are inherently less productive. Ducks displaced to the north historically do not reproduce well, and those that remained in the prairies in spite of the drought encountered little water or cover for their broods if they attempted to nest. Mallards, blue-winged teal, and pintails have exhibited poor production in the past under conditions not as severe as those in 1988.

The mallards breeding population in surveyed areas was 10 million birds in 1970, 8 million in 1980, and 6.5 million in 1988. Pintail breeding stocks followed a similar pattern, going from 7 million to 5 million to 2.5 million over the same time intervals. For mallards, this year's breeding population was the second lowest on record. The breeding population of pintails in 1988 is the lowest on record. The fall flight index for ducks in 1988 is 66 million, second only to the 62 million record low in 1985.

After multiple years of very poor conditions, and in consideration of the severity of the drought in 1988, maintenance of basic breeding populations is now our primary objective, especially since we know these populations have not produced well this year. Further, we are convinced that the impacts will persist for some time even if weather patterns change. Continued high harvest rates on populations with poor recruitment are not in the best interest of the resource, or the future of waterfowl hunting. For these reasons, the Service is proposing hunting season frameworks significantly different from those in previous years. We are proposing, at a minimum, an additional reduction in havest of the same magnitude as that reached by changes implemented in 1985 and maintained through 1987. The substantial reductions proposed for duck season lengths, framework dates, and bag limits, as well as delayed shooting hours, are strong measures designed to reduce hunting opportunity in order to reduce harvest. In addition, suspension of some special seasons and reevaluation of harvest systems will provide a better basis for future decisions about employment of the point system, zoning and split seasons, and other regulations. Many of the premises behind special seasons and other mechanisms in place before this year were developed to allow increased harvest opportunity at a time when populations were judged capable of providing it. The Service feels that many of these regulations are not consistent with the current status of the duck resource and should be reviewed.

Because these cited problems are not a single-year phenomenon, but rather indicate some strong trends over many years, we are concerned about next year as well. Habitat conditions may not recover next year and, in fact, some duck populations may deteriorate further. On a long-term basis, we are certain that recovery will take at least several years of good climatic conditions, and probably will require direct habitat management to give populations the best chance of recovery in the future. If current habitat and population trends continue, further restrictions may be necessary in the future, perhaps as early as 1989.

Review of Comments Received at Public Hearing

Twenty-four statements were offered at the August 3, 1988, public hearing. Portions of some of these statements were related to matters outside the purpose of the hearing. Each statement

is summarized by category below and was considered in the development of these proposed late-seasons frameworks. The comments below pertain to the proposals presented at the public hearing. However, the proposals contained herein encompass several regulatory changes not reviewed at the public hearing, namely opening shooting hours, suspension of the point system, modification of bag limits on mallards in the Pacific Flyway, and a limited season on pintails. Therefore, responses to the public hearing comments are deferred and will be incorporated into responses to comments received in reply to this document and published with the final frameworks for late seasons.

Regulations Process

Mr. Brian O'Neill, a trial lawyer retained by the Humane Society of the United States, announced that he intends to explore the Service's process for establishing hunting regulations to insure compliance with National Environmental Policy Act, the Migratory Bird Treaty Act, and other applicable laws and regulations. Questions will be posed such as: does the hunting season structure provide adequate protection to species such as black ducks, pintails, canvasbacks, and others, and does the decision process take a hard look at a "no season" alternative to protect ducks? He stated that the Supplemental Environmental Impact Statement (SEIS-88) on migratory bird hunting, completed in 1988, does not do this, and this alternative must be considered. He further stated that annual consideration of a "no season" alternative may relieve some hunting pressure and tells the hunting public that business is not "as usual."

1. Shooting Hours

Mr. John Anderson, representing the National Audubon Society, suggested that starting the duck season at noon on opening day and thereafter begin shooting at sunrise, rather than one-half hour before sunrise, would reduce the harvest of ducks.

2. Frameworks for Ducks in the Conterminous United States—Outside Dates, Season Length and Bag Limits

a. General Harvest Strategy

Twenty-two of 24 persons making presentations at the public hearing addressed the Service Regulations Committee's recommended frameworks for duck regulations. Of those addressing the recommended strategy for reducing harvests of ducks, 11 offered qualified support, 8 believed that the recommended frameworks should be more restrictive, and 3 believed frameworks proposed for the Atlantic Flyway were inappropriate and too restrictive.

Mr. Eldridge Hunt, representing the Pacific Flyway Council, believed the recommended frameworks for ducks were reasonable for protecting waterfowl wintering in the Pacific Flyway. Mr. Dale Strickland, representing the Central Flyway Council, Mr. Hugh Bateman, representing the Mississippi Flyway Council's Southern Region, and Mr. Ken Babcock, representing the Mississippi Flyway Council's Northern Region, supported restrictive regulations but objected that the Service had not indicated earlier that special strategies should be developed to further reduce harvests of mid-continent mallards. They further indicated that the Councils discussed the need for such further action and would have been willing to try to develop regulations appropriately if the Service had provided such direction. Modifications of Council recommendations by the Service Regulations Committee would result in inequities in harvest opportunities, an erosion of the point system, and potential for increased harvests of several species. Mr. Leon Kirkland, representing the Atlantic Flyway Council, generally supported a strategy of reducing harvests on most duck species, but did not believe that the degree of reduction should be as great for the Atlantic Flyway as for other Flyways since a smaller proportion of Atlantic Flyway ducks are derived from the areas most stressed by drought and poor nesting conditions. Mr. Charles Potter, representing the North American Wildlife Foundation, stated that ducks need protection now more than ever and if major restrictions are not implemented, credibility with hunters will be lost. He suggested that a level protection at least equal to that given during the drought years of 1961 to 1964 would be appropriate this year. Mr. Jack Lorenz, representing the Izaak Walton League, supported the recommendations of the North American Wildlife Foundation. Mr. Jim Phillips, writer and duck hunter, believed that the proposed harvest strategy is not restrictive enough and recommended a general harvest reduction of about 50 percent. Mr. George Reiger, representing *Field & Stream* magazine, voiced concern by his readership over the status of ducks and need for restrictive measures, perhaps even season closures. Mr. Doug Inkley, National Wildlife Federation, generally supported the season reductions proposed by the Service. Mr. Mike Berger, representing Ducks Unlimited, Inc., Mr. Steve Miller, representing the Wisconsin Department of Natural Resources, and Mr. Roger Holmes, representing the Minnesota Department of Natural Resources, all expressed general support for the proposed strategy to reduce duck harvests. On behalf of the National Audubon Society, Mr. John Anderson supported the strategy to reduce hunting opportunity by at least 25 percent, but suggested some alternative measures to accomplish this reduction. Mr. James Yoos and Mr. Stanley Nadler, representing the New Jersey Waterfowler's Association, expressed concern that the proposed strategy unfairly restricted the Atlantic Flyway and suggested that harvest reductions should be focused on the areas where the specific problems are occurring. Mr. John Viser, representing the Berry Brooks Foundation, and citizen Grayson Chesser both suggested that the strategy of reducing duck harvest by 25 percent, while commendable, is not adequate and both suggested a reduction of 50 percent would be more appropriate.

b. Framework Dates

Mr. Steve Miller, representing the Wisconsin Department of Natural Resources, endorsed the proposed October 8-January 8 framework opening and closing dates for duck hunting. Mr. Doug Inkley, representing the National Wildlife Federation, endorsed the January 8 closing date. Mr. Leon Kirkland, representing the Atlantic Flyway Council, recommended that the framework closing date be January 15 instead of January 8, stating that the best hunting opportunity in the southern part of the flyway occurs after January 1, and citing previous experience with a January 13 closing date which resulted in reduced harvests.

c. Season Length

Representatives of eight organizations commented on the season lengths proposed by the Service. Mr. Doug Inkley, representing the National Wildlife Federation, Mr. Charles Potter, representing the North American Wildlife Foundation, and Mr. Jack Lorenz, representing the Izaak Walton League, generally supported the Service recommendations for shorter seasons. Mr. Leon Kirkland, representing the Atlantic Flyway Council, while supporting some reduction in season length, disagreed with a 25 percent reduction for the Atlantic Flyway, citing the comparatively small proportion of prairie-nesting mallards, blue-winged teal and pintails (species which are most

affected by the drought) that are harvested in the Atlantic Flyway. Mr. Kirkland stated that only 2.8 percent of the harvest of prairie-nesting mallards occurs in the Atlantic Flyway, and percentages are similar to this for blue-winged teal and pintails. He noted that the predicted fall flight into the Atlantic Flyway is not forecast to be significantly changed from that in 1987. He recommended that the season length in the Atlantic Flyway be 35 days, which would be a 12.5 percent reduction from 1987. Jim Phillips, writer and duck hunter, recommended a 30-day season nationwide, while Mr. John Anderson of the National Audubon Society recommended a 25-day season nationwide. Mr. Roger Holmes, representing the Minnesota Department of Natural Resources, asked that an additional 5-day reduction in season length in the Mississippi and Central Flyways, over and above the 25 percent reduction proposed by the Service, be considered if mallard point values were returned to 35 points. Mr. Richard Bishop, representing the Iowa Department of Natural Resources, suggested that further reductions in season length would be preferable to further reductions in the mallard bag limit.

d. Closed Seasons

Mr. Charles Potter, representing the North American Wildlife Foundation, and Mr. Doug Inkley, representing the National Wildlife Federation, endorsed a season closure on canvasback and pintails. Mr. Bill Nickel, representing the Eastern Shore Waterfowl Trust, called for consideration of planned closures for the purpose of stockpiling breeding ducks. He suggested that targeting a closed season now for some future date would have hunter support. Mr. Lewis Regenstein, representing the Fund for Animals, provided written comment at the public hearing in support of a closed season.

e. Bag Limits

Messrs. Kenneth Babcock and Hugh Bateman, representing the Mississippi Flyway Council, Mr. Dale Strickland, representing the Central Flyway Council, and Mr. Richard Bishop, representing the Iowa Department of Natural Resources, while recognizing the need for harvest reductions in mallards and other species, opposed a decreased bag limit for mallard drakes from 1987. The comments were specifically directed toward the possible change in point value under the point system. They generally believe that such a change is not warranted because other restrictions being proposed, such as reduced season lengths and framework dates, would accomplish the desired reduction in mallard harvest. They further suggest that such a change in point values is an attempt to force elimination of the point system and would actually redirect hunting pressure toward female mallards and other species. Messrs. Bishop and Babcock noted that the point system is more restrictive than the conventional bag limit and the reduced attractiveness of the point system with a 70-point mallard drake will force some states currently selecting the point system to adopt the conventional bag limit which, they believe, will result in a higher kill of mallard hens than under the point system. Mr. John Anderson, representing the National Audubon Society, recommended a simplified 2-duck daily bag limit with no species or sex restrictions. Mr. Anderson noted that, while such a bag limit would seem to be a liberalization on species and sexes for which only 1 is allowed at present, this would be preferable to a complicated point system and would eliminate identification problems. Mr. Anderson cited studies from 1971 that suggested high point birds were discarded by hunters at a greater rate than low point birds. He also referred to a survey he conducted of more than 100 law-enforcement agents in which only two believed that the point system is enforceable. He further cited a recent analysis of the effectiveness of the point system in directing hunting pressure toward drake mallards and away from hens which concluded that the point system regulations have not successfully done this. *Field & Stream* Conservation Editor George Reiger identified a number of problems with enforcement of and compliance with the point system and suggested that the system was not working as intended.

7. Extra Teal Option

Mr. Leon Kirkland, representing the Atlantic Flyway Council, recommended that blue-winged teal be suspended as part of the teal bonus but requested that green-winged teal continue to be offered with 2 birds daily for 9 consecutive hunting days. He stated that greenwings have been part of the extra teal bag in the flyway since 1979 without adverse effects and breeding populations are 46 percent above objective levels.

14. Frameworks for Geese and Brant in the Conterminous United States—Outside Dates, Season Length, and Bag Limits

Mr. Douglas Inkley, representing the National Wildlife Federation, endorsed the proposed continuation of all goose frameworks, especially the conservative regulations for certain populations of Pacific Flyway geese. Mr. Richard Elden, representing the Michigan Department of Natural Resources, opposed reduction in Canada goose bag limits in the southeastern portion of the State to provide added protection to Tennessee Valley Population (TVP) Canada geese. Recent data suggest that some of these geese migrate to wintering areas in southern portions of the Atlantic Flyway, where populations are declining. Mr. Elden stated that Michigan has previously taken measures to protect TVP geese by selecting shorter hunting seasons than the flyway frameworks permit and establishing a quota zone in one of the principal harvest areas to control harvest. Further, the State is establishing a new quota zone in another important harvest area this year. He requested that the bag limits be the same as last year.

15. Tundra Swans

Ms. Jennifer Lewis, representing the Humane Society of the United States, stated that there is no justification for tundra swan seasons in the Atlantic Flyway. She indicated that the overall good population status and depredation on grain fields by tundra swans should not be used as reasons for encouraging hunting seasons on this species.

Mr. Doug Inkley, representing the National Wildlife Federation, expressed support for tundra swan seasons proposed in New Jersey and Virginia and the existing season in North Carolina.

Written Comments Received

In the **Federal Register** dated June 7, 1988 (53 FR 20874), the Service reviewed comments on proposed season frameworks received from 48 correspondents as of May 9, 1988. In the **Federal Register** dated July 11, 1988 (53 FR 26198), the Service reviewed additional comments received through June 22, 1988. Since then, further comments have been received. Those received as of August 4 are summarized here by regulatory topics arranged in the same order as in the March 9, 1988, **Federal Register** (53 FR 7702).

Regulations Process

One individual requested that the Service reevaluate the process for receiving public comments because some Mississippi waterfowl hunters reported they were denied the opportunity to comment via telephone.

1. Shooting Hours

In order to provide additional protection for ducks in 1988–89, the Illinois Department of Conservation and one individual recommended restriction of daily shooting hours to include sunrise opening and pre-sunset closure. One waterfowl organization and one individual recommended either restricting daily shooting hours or allowing hunting only certain days of the week.

2. Frameworks for Ducks in the Conterminous United States—Outside Dates, Season Length, and Bag Limits

a. General Harvest Strategy—Because of concern about the status of ducks and their habitats, Mississippi Department of Wildlife Conservation supported reduction of the 1988 duck harvest by at least 50 percent below those during the period of stabilized regulations. Also, two individuals urged severe restrictions in hunting but urged all interested parties to continue to provide habitat for ducks. Another individual said that regulations should be made simple because he believed that complex regulations contributed to a decline in the number of hunters which in turn would result in reduced support for maintaining waterfowl habitats. Two individuals questioned whether the governments of Mexico and Canada would impose restrictions on duck harvests comparable to those deemed necessary in the U.S.; and, if not, urged the Service to seek their cooperation in doing so.

b. Framework dates—The Illinois Department of Conservation recommended that framework dates on both ends be shortened by 7–10 days. The Mississippi Department of Wildlife Conservation, while supporting restrictions on duck harvests, believed that outside framework dates of October 8 and January 1 suggested by the Office of Migratory Bird Management would disproportionately impact southern States. In a subsequent letter, Mississippi supported the adoption of the Mississippi Flyway Council's proposed frameworks of October 8 and January 8, although they believe a later framework closing date is warranted.

Four individuals, while supporting restriction of most regulations, urged that season ending dates be later, generally January 14 to 20, because ducks tended not to arrive in the southern States until later in the year.

c. *Season length.*—The Illinois Department of Conservation, *Sports Afield*, one waterfowl organization, and three individuals recommended reducing the length of the hunting season to help reduce the harvest of ducks. One individual and the Concerned Coastal Sportsman's Association recommended longer seasons in the Atlantic Flyway to compensate for hunting days lost because Sunday hunting is prohibited in many States. One individual and the Concerned Coastal Sportsman's Association recommended longer seasons in 1988–89.

d. *Closed season*—Due to the depressed status of continental duck populations, current drought conditions, and expected low production of young in 1988, 30 individuals, the Wisconsin Waterfowlers Association, the Wildlife Management Institute, and the North American Wildlife Foundation, provided written comment in support of a closed season. Many stated their overall commitment to duck hunting, but out of concern for the resource they urged the Service to cancel the duck season this year. One individual opposed a season closure until comprehensive harvest management plans have been developed with Canada and Mexico. Another opposed closing the duck season for fear that the season would be kept from reopening.

e. *Bag limits*—Eighteen written comments were received specifically regarding bag limits. The Illinois Department of Conservation proposed a number of general hunting restrictions, including elimination of the point system. They also recommended a simplified bag limit of 3 ducks, only 2 of which may be of the same species and only one female of any species. Two individuals recommended a simple 4-duck daily bag limit nationwide, and two others suggested a simple 3-duck bag limit. Six individuals recommended elimination of the point system, due primarily to difficulty with identification of duck species and sexes or to a perception that the point system is more liberal than a fixed bag-limit system. One individual suggested that the point value of pintails be increased to 70 or 100 points, while another suggested lowering the bag limit on pintails and mallards by 1 and eliminating restrictions on sexes due to identification problems with hens. The Minnesota Waterfowl Association suggested raising the point value of mallard drakes to 55 to reduce the harvest. Three individuals called for general reductions in bag limits. The Concerned Coastal Sportsman's Association recommended that the mallard limit be increased, and one individual recommended an increase in duck possession limits to 3 times the daily bag limit due to the long distances travelled and several days spent on hunting trips.

3. Black Ducks

The New Jersey Waterfowler's Association, the Concerned Coastal Sportsman's Association and one individual commented that regulations on black ducks for the 1988–89 season should remain similar to last year or should be liberalized to 2 birds daily with a shortened season. They indicate that black duck numbers have remained stable and have reached population levels that exceed available wintering habitat. One individual called for a closed season on black ducks.

7. Extra Teal Option

The Concerned Coastal Sportsman's Association expressed their support for continuing the 2-bird bonus on green-winged teal during 9 days of the regular season.

9. Special Scaup Season

The Concerned Coastal Sportsman's Association requested a continuation of the 16-day scaup season outside the regular season dates.

13. Duck Zones

The Concerned Coastal Sportsman's Association requested the continuation of zoning in Massachusetts. The Wyoming Game and Fish Department asked that zones be dropped in their State to simplify regulations and that they be allowed to split their season 3 ways. The Kansas Department of Wildlife and Parks expressed their opposition to the Service's position on zoning. They believe that if zoning has been allowed in some States, it should then be available to other States pending an evaluation based on the established criteria. The Louisiana Department of Wildlife and Fisheries and one individual expressed opposition to the Service's action to keep the western zone of Louisiana in the Mississippi Flyway. They stated that this position is not justified based on results of an extensive research study and that final decisions were based arbitrarily on political motives.

14. Frameworks for Geese and Brant in the Conterminous United States—Outside Dates, Season Length and Bag Limits

Atlantic Flyway. One individual recommended that the brant season be increased to 50 days. The Concerned Coastal Sportsman's Association also recommended this increase and in addition, a longer Canada goose season. One individual recommended that goose hunting be permitted only during the latter part of each week. One individual recommended that the goose bag limit

be increased to 3 in 1989–90. The Pennsylvania Game Commission recommended that the Canada goose bag limit be increased to 3 in the northwestern part of the State around Pymatuning Reservoir. The Delaware Department of Natural Resources and Environmental Control recommended a special 13-day snow goose season in October on and around Bombay Hook National Wildlife Refuge. The New Jersey Department of Environmental Protection recommended they be permitted to select brant and snow goose seasons separately within their respective duck zones.

Mississippi Flyway. One individual supported the special early and late seasons to harvest local giant Canada geese in Michigan. One individual recommended that if longer goose seasons are provided for Illinois, the same season length be made available for the entire State rather than part of the State.

Central Flyway. One individual recommended a later framework closing date for Canada goose hunting in Texas.

Pacific Flyway. Four individuals and the Oregon Farm Bureau recommended that the Canada goose season framework be extended to February 15 in parts of western Oregon, and the Farm Bureau recommended hunting only on alternate days for geese and shooting hours beginning at 8:00 a.m. instead of 9:00 a.m.

15. Tundra Swans

As of August 4, 1988, the Service has received nearly 2000 postcards and letters, nearly all from individuals urging that swans not be hunted. Most comments requested "* * * not to lift federal restrictions on swan hunting." following the wording in a flyer distributed by the National Humane Education Society (no address, phone number or date given). The New Jersey Waterfowler's Association offered support for a limited season on tundra swans in New Jersey to reduce crop losses.

Public Comments

Based on the results of recently-completed migratory game bird studies, and having due consideration for any data or views submitted by interested parties, the amendments resulting from these supplemental proposals will specify open seasons, shooting hours, areas, and bag and possession limits for waterfowls and coots.

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process.

The Director intends that finally-adopted rules be as responsive as possible to all concerned interests. He therefore desires to obtain the comments and suggestions of the public, other concerned governmental agencies, and private interests on these proposals and will take into consideration the comments received. Such comments, and any additional information received, may lead the Director to adopt final regulations differing from these proposals.

Special circumstances are involved in the establishment of these regulations which limit the amount of time which the Service can allow for public comment. Specifically, two considerations compress the time in which the rulemaking process must operate: the need, on the one hand, to establish final rules at a point early enough in the summer to allow affected State agencies to appropriately adjust their licensing and regulatory mechanisms, and, on the other hand, the unavailability before late July of specific, reliable data on this year's status of waterfowl. Therefore, the Service believes that to allow a comment period past August 25, 1988, is contrary to the public interest.

Comment Procedure

Interested persons may participate by submitting written comments on the Director (FWS/MBMO), U.S. Fish and Wildlife Service, Department of the Interior, Matomic Building, Room 536, Washington, DC 20240. Comments received will be available for public inspection during normal business hours at the Service's office in Room 536 in the Matomic Building, 1717 H Street NW., Washington, DC.

All relevant comments received on the late season proposals no later than August 25, 1988, will be considered. The Service will attempt to acknowledge all comments received, but substantive response to individual comments may not be provided.

Nontoxic Shot Regulations

In the June 28, 1988, **Federal Register** (53 FR 24284), the Service published a final rule describing zones in which lead shot is prohibited for hunting waterfowl, coots and certain other species in the 1988–89 season. Waterfowl hunters are advised to become familiar with State and local regulations regarding the use of nontoxic shot for waterfowl hunting.

NEPA Consideration

The "Final Environmental Statement for the Issuance of Annual Regulations Permitting the Sport Hunting of Migratory Birds (FES–75–54)" was filed with the Council on Environmental Quality (CEQ) on June 6, 1975, and notice of availability was published in the **Federal Register** on June 13, 1975 (40 FR 25241). A supplement to the FES, "Final Supplemental Environmental Impact Statement: Issuance of Annual Regulations Permitting the Sport Hunting of Migratory Birds (FSES 88–14)", was filed with CEQ on June 9, 1988, and Notice of Availability was published in the **Federal Register** on June 16, 1988 (53 FR 22582), and June 17, 1988 (53 FR 22727).

Endangered Species Act Consideration

Section 7 of the Endangered Species Act provides that, "The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this Act" "[and shall] by taking such action necessary to insure that any action authorized, funded, or carried out * * * is not likely to jeopardize the continued existence of such endangered or threatened species or result in the destruction or modification of [critical] habitat * * *"

Consequently, the Service initiated Section 7 consultation under the Endangered Species Act for the proposed hunting season frameworks.

On June 17, 1988, the Chief, Division of Endangered Species and Habitat Conservation, gave a biological opinion that the proposed action was not likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of their critical habitats.

The Service's biological opinion resulting from its consultation under section 7 of the Endangered Species Act is available for public inspection in or available from the Division of Endangered Species and Habitat Conservation and the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240.

Regulatory Flexibility Act, Executive Order 12291, and the Paperwork Reduction Act

In the **Federal Register** dated March 9, 1988 (53 FR 7702), the Service reported measures it had undertaken to comply with requirements of the Regulatory Flexibility Act and the Executive Order. These included preparing a Determination of Effects and an updated Final Regulatory Impact Analysis, and publication of a summary of the latter. These regulations have been determined to be major under Executive Order 12291 and they have a significant economic impact on substantial numbers of small

entities under the Regulatory Flexibility Act. This determination is detailed in the aforementioned documents which are available upon request from the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240. These proposed regulations contain no information collections subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980.

Memorandum of Law

The Service published its Memorandum of Law, required by Section 4 of Executive Order 12291, in the **Federal Register** dated August 9, 1988 (53 FR 29897).

Authorship

The primary author of this proposed rule is Morton M. Smith, Office of Migratory Bird Management, working under the direction of Rollin D. Sparrowe, Chief.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Transportation, Wildlife.

The rules that eventually will be promulgated for the 1988–89 hunting season are authorized under the Migratory Bird Treaty Act of July 3, 1918 (40 Stat. 755; 16 U.S.C. 701–708h); the Fish and Wildlife Improvement Act of 1978 (92 Stat. 3112; 16 U.S.C. 712); and the Alaska Game Act of 1925 (43 Stat. 739; as amended, 54 Stat. 1103–04)

Proposed Regulations Frameworks for 1988–89 Late Hunting Seasons on Certain Migratory Game Birds

Pursuant to the Migratory Bird Treaty Act, the Secretary of the Interior has approved proposed frameworks for season lengths, shooting hours, bag and possession limits and outside dates within which States may select seasons for hunting waterfowl and coots. Frameworks are summarized below.

General

Split Season

States in all Flyways may split their season for ducks, geese or brant into two segments. States in the Atlantic and Central Flyways may, in lieu of zoning, split their season for ducks or geese into three segments. Exceptions are noted in appropriate sections.

Shooting Hours

From sunrise to sunset daily, for all species and seasons, including falconry seasons.

Deferred Season Selections

States that did not select rail, woodcock, snipe, sandhill cranes, common moorhens and purple gallinules and sea duck seasons in July should do so at the time they make their waterfowl selections.

Frameworks for open seasons and season lengths, bag and possession limit options, and other special provisions are listed below by Flyway.

ATLANTIC FLYWAY

The Atlantic Flyway includes Connecticut, Delaware, Florida, Georgia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, Vermont, Virginia and West Virginia.

Ducks, Coots and Mergansers

Hunting Seasons and Duck Limits:

Outside Dates: Between October 8, 1988, and January 8, 1989.

Hunting Season: Not more than 30 days.

Canvasbacks: The season on canvasbacks is closed.

Duck Limits: The daily bag limit of ducks is 3 and may include no more than 3 mallards (only 1 may be a hen), 2 wood ducks, 2 redheads, 1 black duck and 1 fulvous tree duck. For pintails, the daily bag limit during the first 7 days of the hunting season is 1. During the last 7 days of the season, the daily bag limit is 2 male pintails. During the period between the first 7 days and the last 7 days, the season on pintails is closed. The possession limit is twice the daily bag limit.

Merganser Limits: Throughout the Flyway the daily bag limit of mergansers is 5, only 1 of which may be a hooded merganser. The possession limit is 10, only 2 of which may be hooded mergansers.

Coot Limits: Throughout the Flyway daily bag and possession limits of coots are 15 and 30, respectively.

Early Wood Duck Season Option: Virginia, North Carolina, South Carolina and Georgia may split their regular hunting season so that a hunting season not to exceed 9 consecutive days occurs between October 8 and October 16. During this period, no special restrictions within the regular daily bag and possession limits established for the Flyway shall apply to wood ducks. For other ducks, daily bag and possession limits shall be the same as established for the Flyway.

Restriction on Mottled Ducks: The season is closed to the taking of mottled ducks in South Carolina.

Zoning—New York: New York may, for the *Long Island Zone*, select season dates and daily bag and possession limits which differ from those in the remainder of the State.

Upstate New York (excluding the Lake Champlain zone) may be divided into three zones (West, North, South) for the purpose of setting separate duck, coot and merganser seasons. A 2-segment split season may be selected in each zone.

The *West Zone* is that portion of upstate New York lying west of a line commencing at the north shore of the Salmon River and its junction with Lake Ontario and extending easterly along the north shore of the Salmon River to its intersection with Interstate Highway 81, then southerly along Interstate Highway 81 to the Pennsylvania border.

The *North* and *South Zones* are bordered on the west by the boundary described above and are separated from each other as follows: starting at the intersection of Interstate Highway 81 and State Route 49 and extending easterly along State Route 49 to its junction with State Route 365 at Rome, then easterly along State Route 365 to its junction with State Route 28 at Trenton, then easterly along State Route 28 to its junction with State Route 29 at Middleville, then easterly along State Route 29 to its intersection with Interstate Highway 87 at Saratoga Springs, then northerly along Interstate Highway 87 to its junction with State Route 9, then northerly along State Route 9 to its junction with State Route 149, then easterly along State Route 149 to its junction with State Route 4 at Fort Ann, then northerly along State Route 4 to its intersection with the New York/Vermont boundary.

Connecticut may be divided into two zones as follows:

a. *North Zone*—That portion of the State north of Interstate 95.

b. *South Zone*—That portion of the State south of Interstate 95.

Maine may be divided into two zones as follows:

a. *North Zone*—Game Management Zones 1 through 5.

b. *South Zone*—Game Management Zones 6 through 8.

New Hampshire—Coastal Zone—That portion of the State east of a boundary formed by State Highway 4 beginning at the Maine-New Hampshire line in Rollinsford west to the city of Dover, south to the intersection of State Highway 108, south along State Highway 108 through Madbury, Durham and Newmarket to the junction of State Highway 85 in Newfields, south to State Highway 101 in Exeter, east to State

Highway 51 (Exeter-Hampton Expressway), east to Interstate 95 (New Hampshire Turnpike) in Hampton, and south along Interstate 95 to the Massachusetts line.

Inland Zone—That portion of the State north and west of the above boundary.

West Virginia may be divided into two zones as follows:

a. *Allegheny Mountain Upland Zone*—The eastern boundary extends south along U.S. Route 220 through Keyser, West Virginia, to the intersection of U.S. Route 50; follows U.S. Route 50 to the intersection with State Route 93; follows State Route 93 south to the intersection with State Route 42 and continues south on State Route 42 to Petersburg; follows State route 28 south to Minnehaha Springs; then follows State Route 39 west to U.S. Route 219; and follows U.S. Route 219 south to the intersection of Interstate 64. The southern boundary follows I-64 west to the intersection with U.S. Route 60, and follows Route 60 west to the intersection of U.S. Route 19. The western boundary follows: Route 19 north to the intersection of I-79, and follows I-79 north to the intersection of U.S. Route 48. The northern boundary follows U.S. Route 48 east to the Maryland State line and the State line to the point of beginning.

b. Remainder of the State—That portion outside the above boundaries.

Zoning Experiments: Vermont will continue a Lake Champlain Zone in 1988. The Lake Champlain Zone of New York must follow the waterfowl season, daily bag and possession limits, and shooting hours selected by Vermont. *Massachusetts, New Jersey,* and *Pennsylvania,* may continue zoning experiments now in progress as shown in the sections that follow. *Massachusetts* and *New Jersey* may be divided into three zones, *Pennsylvania* into four zones and *Vermont* into two zones all on an experimental basis for the purpose of setting separate duck, coot and merganser seasons. A two-segment split season without penalty may be selected. The basic daily bag limit of ducks in each zone and the restrictions applicable to the regular season for the Flyway also apply.

Zone Definitions—Massachusetts—Western Zone—That portion of the State west of a line extending from the Vermont line at Interstate 91, south to Route 9, west on Route 9 to Route 10, south on Route 10 to Route 202, south on Route 202 to the Connecticut line.

Central Zone—That portion of the State east of the Western Zone and west of a line extending from the New Hampshire line at Interstate 95 south to Route 1, south on Route 1 to I-93, south on I-93 to Route 3, south on Route 3 to Route 6, west on Route 6 to Route 28, west on Route 28 to I-95, west to Rhode Island line. *EXCEPT* the waters, and the lands 150 yards along the high-water mark, of the Assonit River to the Route 24 bridge, and the Taunton River to the Center St.-Elm St. bridge shall be in the Coastal Zone.

Coastal Zone—That portion of the State east and south of the Central Zone.

New Jersey—Coastal Zone—That portion of New Jersey seaward of a continuous line beginning at the New York State boundary line in Raritan Bay; then west along the New York boundary line to its intersection with Route 440 at Perth Amboy; then west on Route 440 to its intersection with the Garden State Parkway; then south on the Garden State Parkway to the shoreline at Cape May and continuing to the Delaware boundary in Delaware Bay.

North Zone—That portion of New Jersey west of the Coastal Zone and north of a boundary formed by Route 70 beginning at the Garden State Parkway west to the New Jersey Turnpike, north on the turnpike to Route 206, north on Route 206 to Route 1, Trenton, west on Route 1 to the Pennsylvania State boundary in the Delaware River.

South Zone—That portion of New Jersey not within the North Zone or the Coastal Zone.

Pennsylvania—Lake Erie Zone—The Lake Erie waters of Pennsylvania and a shoreline margin along Lake Erie from New York on the east to Ohio on the west extending 150 yards inland, but including all of Presque Isle Peninsula.

North Zone—That portion of the State north of I-80 from the New Jersey State line west to the junction of State Route 147; then north on State Route 147 to the junction of Route 220, then west and/or south on Route 220 to the junction of I-80, then west on I-80 to its junctions with the Allegheny River, and then north along but not including the Allegheny River to the New York border.

Northwest Zone—That portion of the State bounded on the north by the Lake Erie Zone and the New York line, on the east by and including the Allegheny River, on the south by Interstate Highway I-80, and on the west by the Ohio line.

South Zone—The remaining portion of the State.

Vermont—Lake Champlain Zone—Includes the United States portion of Lake Champlain and those portions of New York and Vermont which includes that part of New York lying east and north of boundary running south from the Canadian border along New York Route 9B to New York Route 9 south of Champlain, New York; New York Route 9 to New York Route 22 south of Keeseville; along New York Route 22 to South Bay, along and around the shoreline of South Bay to New York Route 22; along New York Route 22 to U.S. Highway 4 at Whitehall; and along U.S. Highway 4 to the Vermont border. From the New York border at U.S. Highway 4, along U.S. Highway 4 to Vermont Route 22A at Fair Haven; Route 22A to U.S. Highway 7 at Vergennes; U.S. Highway 7 to the Canadian border.

Interior Vermont Zone—The remaining portion of the State.

Sea Ducks: The daily bag and possession limit for sea ducks in special sea duck areas is in addition to the limits applying to other ducks during the regular duck season. In all areas outside of special sea duck areas, sea ducks are included in the regular duck season daily bag and possession limits.

Canada Geese

Outside Dates, Season Lengths, and Limits: Between October 1, 1988, and January 20, 1989, Maine, New Hampshire, Vermont, Massachusetts, Pennsylvania, and West Virginia may select 70-day seasons for Canada geese with a daily bag and possession limit of 3 and 6 geese, respectively, except in Pennsylvania Counties of Erie, Mercer, Butler, and Crawford, where the daily bag and possession limits are 2 and 4, respectively. In Maryland, Delaware and Virginia (except Back Bay) the Canada goose season may be 70 days with an opening date of October 31, 1988, and a closing date of January 31, 1989, with 2 geese daily and 4 in possession. In New York (including Long Island), New Jersey, and that portion of Pennsylvania lying east and south of a boundary beginning at Interstate Highway 83 at the Maryland border and extending north to Harrisburg, then east on I-81 to Route 443, east on 443 to Leighton, then east via 208 to Stroudsburg, then east on I-80 to the New Jersey line, the Canada goose season length may be 90 days with the opening framework date of October 1, 1988, and the closing framework date extended to January 31, 1989. In addition, that portion of the Susquehanna River from Harrisburg north to the confluence of the west and north branches at Northumberland, including a 25-yard zone of land adjacent to the waters of the river, is included in the 90-day zone. The daily bag and possession limits within this area will be 1 and 2, respectively through October 15, 1988, and 3 and 6,

respectively thereafter. In Rhode Island, and Connecticut (North Zone) season length will be 90 days between October 1, 1988, and January 31, 1989, with a daily bag and possession limit of 3 and 6, respectively. In the South Zone of Connecticut (that portion south of Interstate 95), the Canada goose season length may be 90 days with the closing framework date extended to February 5, 1989. The daily bag limit and possession limit will be 3 and 6, respectively, through January 14, and 5 and 10, respectively from January 15 to February 5, 1989. This season in the South Zone of Connecticut is experimental. The Back Bay of Virginia, North Carolina (that portion south of Interstate Highway 95), and South Carolina may select an 11-day season for Canada geese within a January 20–31, 1989, framework; the daily bag and possession limits are 1 and 2 Canada geese, respectively. In the Coastal Zone of Massachusetts, a special resident Canada goose season may be held during January 21, 1989, to February 5, 1989; the daily bag and possession limits are 5 and 10, respectively.

Closures on Canada geese: The season for Canada geese is closed in Florida and Georgia.

Snow Geese

Outside Dates, Season Lengths, and Limits: Between October 1, 1988, and January 31, 1989, States in the Atlantic Flyway may select a 90-day season for snow geese (including blue geese); the daily bag and possession limits are 4 and 8, respectively. Between October 17, 1988, and October 29, 1988, a special snow goose season may be held in Delaware on Bombay Hook National Wildlife Refuge and immediate area (as described in State regulations) at the discretion of the Refuge Manager. Daily bag and possession limits are 4 and 8, respectively. This season is in addition to the 90-day regular season.

Atlantic Brant

Outside Dates, Season Lengths, and Limits: Between October 1, 1988, and January 20, 1989, States in the Atlantic Flyway may select a 50-day season for Atlantic brant; the daily bag and possession limits are 2 and 4 brant, respectively.

Tundra Swans

In New Jersey, Virginia and North Carolina an experimental season for tundra swans may be selected with 200, 600 and 6,000 permits, respectively, subject to the following conditions: (a) the season may be 90 days and must run concurrently with the snow goose season; (b) the State agency must issue and obtain harvest and hunter participation data; and (c) each permittee is authorized to take 1 tundra swan per season.

MISSISSIPPI FLYWAY

The Mississippi Flyway includes Alabama, Arkansas, Illinois, Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Ohio, Tennessee and Wisconsin.

Ducks, Coots, and Mergansers

Outside Dates: Between October 8, 1988, and January 8, 1989, in all States.

Hunting Season: Not more than 30 days.

Canvasbacks: The season on canvasbacks is closed.

Limits: The daily bag limit of ducks is 3, and may include no more than 2 mallards (no more than 1 of which may be a female), 1 black duck, 2 wood ducks, and 1 redhead. For pintails, the daily bag limit during the first 7 days of the hunting season is 1. During the last 7 days of the season, the daily bag limit is 2 male pintails. During the period between the first 7 days and the last 7 days, the season on pintails is closed. The possession limit is twice the daily bag limit.

Merganser Limits: The daily bag limit of mergansers is 5, only 1 of which may be a hooded merganser. The possession limit is twice the daily bag limit.

Coot Limits: The daily bag and possession limits are 15 and 30, respectively.

Early Wood Duck Season Option: Arkansas, Louisiana, Mississippi and Alabama may split their regular duck hunting seasons in such a way that a hunting season not to exceed 9 consecutive days may occur between October 8 and October 16. During this period, no special restrictions within the regular daily bag and possession limits established for the Flyway shall apply to wood ducks. For other species of ducks, daily bag and possession limits shall be the same as established for the Flyway. This exception to the daily bag and possession limits for wood ducks shall not apply to that portion of the duck hunting season that occurs after October 16.

Pymatuning Reservoir Area, Ohio: The waterfowl seasons, limits and shooting hours in the Pymatuning Reservoir area of Ohio will be the same as those selected by Pennsylvania. The area includes Pymatuning Reservoir and that part of Ohio bounded on the north by County Road 306 known as Woodward Road, on the west by Pymatuning Lake Road, and on the south by U.S. Highway 322.

Zoning—Alabama, Illinois, Indiana, Iowa, Louisiana, Michigan, Missouri, Ohio, Tennessee, and *Wisconsin* may select hunting seasons for ducks, coots and mergansers by zones described as follows:

Alabama: South Zone—Mobile and Baldwin Counties. North Zone—The remainder of Alabama. The season in the South Zone may be split into two segments.

Illinois: North Zone—That portion of the State north of a line running east from the Iowa border along Illinois Highway 92 to I–280, east along I–280 to I–80, then east along I–80 to the Indiana border. Central Zone—That portion of the State between the North and South Zone boundaries. South Zone—That portion of the State south of a line running east from Missouri border along the Modoc Ferry route to Randolph County Highway 12, north along Highway 12 to Illinois Highway 3, north along Illinois Highway 3 to Illinois Highway 159, north along Illinois Highway 159 to Illinois Highway 161, east along Illinois Highway 161 to Illinois Highway 4, north along Illinois Highway 4 to I–70, then east along I–70 to the Indiana border.

Indiana: North Zone—That portion of the State north of a line extending east from the Illinois border along State Highway 18 to U.S. Highway 31, then north along U.S. 31 to U.S. Highway 24, then east along U.S. 24 to Huntington, the southeast along U.S. Highway 224 to the Ohio border. Ohio River Zone: That portion of Indiana south of a line extending east from the Illinois border along Interstate Highway 64 to New Albany, then east along State Highway 62 to State Highway 56, then east along State Highway 56 to Vevay, then on State Highway 156 along the Ohio River to North Landing, then north along State Highway 56 to U.S. Highway 50, then northeast along U.S. 50 to the Ohio border. South Zone—That portion of the State between the North and Ohio River Zone boundaries. The season in each zone may be split into two segments.

Iowa: North Zone—That portion of Iowa north of a line running west from the Illinois border along I–80 to U.S. 59, north along U.S. 59 to State Highway 37, northwest along State Highway 37 to State Highway 175, then west along State Highway 175 to the Nebraska border. South Zone—the remainder of the State.

Louisiana: West Zone—That portion of the State west of a boundary beginning at the Arkansas-Louisiana border on Louisiana Highway 3, then south along Louisiana Highway 3 to Bossier City, east along Interstate 20 to

Minden, south along Louisiana Highway 7 to Ringgold, east along Louisiana Highway 4 to Jonesboro, south along U.S. Highway 167 to Lafayette, southeast along U.S. Highway 90 to Houma, south along the Houma Navigation Channel to the Gulf of Mexico through Cat Island Pass. East Zone—The remainder of Louisiana. The season in each zone may be split into two segments.

Note.—No additional days are offered for the West Zone since Louisiana is considered part of the Mississippi Flyway as announced in June 7, 1988, Federal Register (53 FR 10876).

Michigan: North Zone—The Upper Peninsula. South Zone—That portion of the State south of a line beginning at the Wisconsin border in Lake Michigan due west of the mouth of Stony Creek in Oceana County; then due east to, and east and south along the south shore of, Stony Creek to Webster Road, east and south on Webster Road to Stony Lake Road, east on Stony Lake and Garfield Roads to M-20, east on M-20 to U.S.-10B.R. in the city of Midland, east on U.S.-10B.R. to U.S.-10, east on U.S.-10 and M-25 to the Saginaw River, downstream along the thread of the Saginaw River to Saginaw Bay, then on a northeasterly line, passing one-half mile north of the Corps of Engineers confined disposal island offshore of the Carn powerplant, to a point one mile north of the Charity islands, then continuing northeasterly to the Ontario border in Lake Huron. Middle Zone—The remainder of the State. Michigan may split its season in each zone into two segments.

Missouri: North Zone—That portion of Missouri north of a line running east from the Kansas border along U.S. Highway 54 to U.S. Highway 65, south along U.S. 65 to State Highway 32, east along State Highway 32 to State Highway 72, east along State Highway 72 to State Highway 21, south along State Highway 21 to U.S. Highway 60 east along U.S. 60 to State Highway 51, south along State Highway 51 to State Highway 53, south along State Highway 53 to U.S. Highway 62, east along U.S. 62 to I-55, north along I-55 to State Highway 34, then east along State Highway 34 to the Illinois border. South Zone—The remainder of Missouri. Missouri may split its season in each zone into two segments.

Ohio: The counties of Darke, Miami, Clark, Champaign, Union, Delaware, Licking, Muskingam, Guernsey, Harrison and Jefferson and all counties north thereof. In addition, the North Zone also includes that portion of the Buckeye Lake area in Fairfield and Perry Counties bounded on the west by State Highway 37, on the south by State Highway 204, and on the east by State Highway 13. Ohio River Zone—The counties of Hamilton, Clermont, Brown, Adams, Scioto, Lawrence, Gallia and Meigs. South Zone—That portion of the State between the North and Ohio River Zone boundaries. Ohio may split its season in each zone into two segments.

Tennessee: Reelfoot Zone—Lake and Obion Counties, or a designated portion of that area. State Zone—The remainder of Tennessee. Seasons may be split into two segments in each zone.

Wisconsin: North Zone—That portion of the State north of a line extending northerly from the Minnesota border along the center line of the Chippewa River to State Highway 35, east along State Highway 35 to State Highway 25, north along State Highway 25 to U.S. Highway 10, east along U.S. Highway 10 to its junction with the Manitowoc Harbor in the city of Manitowoc, then easterly to the eastern State boundary in Lake Michigan. South Zone—The remainder of Wisconsin. The season in the South Zone may be split into two segments.

Geese

Definition: For the purpose of hunting regulations listed below, the term "geese" also includes brant.

Note.—The various zones and areas identified in this section are described in the respective State's regulations.

Outside Dates, Season Lengths and Limits: Between October 1, 1988, and January 22, 1989 (January 31 in Kentucky, Arkansas, Tennessee, Mississippi, and Alabama), States may select 70-day seasons for geese, with a daily bag limit of 5 geese, to include no more than 2 white-fronted geese. The possession limit is 10 geese, to include no more than 4 white-fronted geese. Regulations for Canada geese and exceptions to the above general provisions are shown below by State.

Outside Dates and Limits on Snow and White-fronted Geese in Louisiana: Between October 1, 1988, and February 14, 1989, Louisiana may hold 70-day seasons on snow (including blue) and white-fronted geese by zones established for duck hunting seasons. Daily bag and possession limits are as described above.

Minnesota. In the:

(a) Lac Qui Parle Goose Management Block—the season for Canada geese may extend for 30 days. In the Lac Qui Parle Quota Zone the season will close after 30 days or when 4,000 birds have been harvested, whichever occurs first. Throughout the 5-county area the daily bag limit is 1 Canada goose and the possession limit is 2.

(b) Southeastern Zone—the season for Canada geese may extend for 70 consecutive days. The daily bag limit is 2 Canada geese and the possession limit is 4. In selected areas of the Metro Goose Management Block and in Olmsted County, experimental 10-day late seasons may be held during December to harvest Giant Canada geese. During these seasons, the daily bag limit is 2 Canada geese and the possession limit is 4.

(c) Remainder of the State—the season for Canada geese may extend for 40 days. The daily bag limit is 1 Canada goose and the possession limit is 2.

Iowa: The season may extend for 45 consecutive days. The daily bag limit is 2 Canada geese and the possession limit is 4. The season for geese in the Southwest Goose Zone may be held at a different time that the season in the remainder of the State.

Missouri. In the:

(a) Swan Lake Zone—the season for Canada geese closes after 40 days or when 10,000 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada geese and the possession limit is 4.

(b) Southeast Zone—A 50-day season on Canada geese may be selected, with a daily bag limit of 2 Canada geese and a possession limit of 4.

(c) Remainder of the State—the season for Canada geese may extend for 40 days in the respective duck hunting zones. The daily bag limit is 1 Canada goose, and the possession limit is 2.

Wisconsin: The total harvest of Canada geese in the State will be limited to 68,200 birds. In the:

(a) Horicon Zone—The framework opening date for Canada geese is September 24, and the harvest of Canada geese is limited to 46,100 birds. The season may not exceed 70 days. All Canada geese harvested must be tagged and the total number of tags issued will be limited so that the quota of 46,100 birds is not exceeded.

(b) Theresa Zone—The harvest of Canada geese is limited to 3,000 birds. The season may not exceed 50 days. The bag limit is 1 Canada goose per permittee per 5-day period, with a season limit of 4.

(c) Pine Island Zone—The harvest of Canada geese is limited to 1,000 birds. The season may not exceed 40 days. All Canada geese harvested must be tagged. The daily bag limit is 1 Canada goose per permittee and the season limit is 4. The total number of tags issued will not exceed 1,980.

(d) Collins Zone—The harvest of Canada geese is limited to 2,000 birds. The season may not exceed 40 days. All Canada geese harvested must be tagged. The daily bag limit is 1 Canada goose and the season limit is 4. The total number of tags issued will not exceed 3,900.

(e) Exterior Zone—The harvest of Canada geese is limited to 16,100 birds. The season may not exceed 35 days, except as noted below. Limits are 1 Canada goose daily and 2 in possession, except as noted below. In the Mississippi River subzone, the season for Canada geese may extend for 70 days. Limits are 1 Canada goose daily and 2 in possession through November 19, and 2 daily and 4 in possession thereafter. In the Brown County subzone, a special late season to control local populations of giant Canada geese may be held during December 1–31. The daily bag and possession limits during this special season are 2 and 4 birds, respectively. In the Rock Prairie Zone, a special late season to harvest giant Canada geese may be held between November 5 and December 11. During the late season, the daily bag limit is 1 Canada goose and the possession limit is 2.

In Wisconsin, the progress of the Canada goose harvest must be monitored by zone, and the respective zone's season closed, if necessary, to ensure that the harvest does not exceed the quota stated above.

Illinois: The total harvest of Canada geese in the State will be limited to 74,000 birds. In the:

(a) Southern Illinois Quota Zone—The season for Canada geese will close after 50 days or when 37,000 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada geese and the possession limit is 4.

(b) Rend Lake Quota Zone—The season for Canada geese will close after 50 days or when 11,100 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada geese and the possession limit is 4.

(c) Tri-County Area—The season for Canada geese may not exceed 50 days. The daily bag limit is 2 Canada geese and the possession limit is 4.

(d) Remainder of State—Seasons for Canada geese up to 50 days may be selected by zones established for duck hunting seasons. The daily bag limit is 2 Canada geese and the possession limit is 4.

Michigan: The total harvest of Canada geese in the State will be limited to 79,400 birds. In the:

(a) North Zone—The framework opening date for geese is September 26 and the season for Canada geese may extend for 40 days, except in the Superior Counties Goose Management Area (GMA), where the season will close after 40 days or when 8,000 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada geese and the possession limit is 4.

(b) Middle Zone—The season for Canada geese may extend for 40 days. The daily bag limit is 2 Canada geese and the possession limit is 4.

(c) South Zone:

(1) Allegan County GMA—the season for Canada geese will close after 50 days or when 4,500 birds have been harvested, whichever occurs first. The daily bag limit is 1 Canada goose and the possession limit is 2.

(2) Muskegon Wastewater GMA—the season for Canada geese will close after 50 days or when 500 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada geese and the possession limit is 4.

(3) Saginaw County GMA—the season for Canada geese will close after 50 days or when 4,500 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada geese and the possession limit is 4.

(4) Fish Point GMA—the season for Canada geese will close after 50 days or when 2,500 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada geese and the possession limit is 4.

(5) Remainder of South Zone—the season for Canada geese may extend for 40 days. The daily bag limit is 2 Canada geese and the possession limit is 4.

(d) Southern Michigan GMA—A late Canada goose season of up to 30 days may be held between January 7 and February 5, 1989. The daily bag limit is 2 Canada geese and the possession limit is 4.

Ohio: The daily bag limit is 2 Canada geese and the possession limit is 4.

Indiana: The total harvest of Canada geese in the State will be limited to 28,400 birds. In:

(a) Posey County—The season for Canada geese will close after 50 days or when 8,300 birds have been harvested, whichever occurs first. The daily bag limit is 2 Canada geese and the possession limit is 4. The season may extend to January 31, 1989.

(b) Remainder of the State—The season for Canada geese may extend for 70 days. The daily bag limit is 2 Canada geese and the possession limit is 4.

Kentucky: In the:

(a) West Kentucky Zone—The season for Canada geese may extend for 50 days, and the harvest will be limited to 22,500 birds. Of the 22,500-bird quota, 14,200 birds will be allocated to the Ballard Subzone and 4,500 birds will be allocated to the Henderson-Union Subzone. If the quota in either subzone is reached prior to completion of the 50-day season, the season in that subzone will be closed. If this occurs, the season in those counties and portions of counties outside of, but associated with, the respective subzone (listed in State regulations) may continue for an additional 7 days, not to exceed a total of 50 days. The daily bag limit is 2 Canada geese and the possession limit is 4.

(b) Remainder of the State—The season may extend for 70 days. The daily bag limit is 2 Canada geese and the possession limit is 4.

Tennessee: In the:

(a) Northwest Zone—The season for Canada geese may extend for 50 days, and the harvest will be limited to 8,900 birds. Of the 8,900-bird quota, 6,200 birds will be allocated to the Reelfoot Subzone. If the quota in the Reelfoot Subzone is reached prior to completion of the 50-day season, the season in the subzone will be closed. If this occurs, the season in the remainder of the Northwest Zone may continue for an addition 7 days, not to exceed a total of 50 days. The daily bag limit is 2 Canada geese and the possession limit is 4.

(b) Southwest Zone—The season for Canada geese may extend for 15 days. The daily bag limit is 1 Canada and the possession limit is 2.

(c) Remainder of the State—The season for Canada geese may extend for 70 days. The daily bag limit is 2 Canada geese and the possession limit is 4.

Arkansas: The total harvest of Canada geese in the State will be limited to 2,400 birds. The season for Canada geese may extend for 16 days. The daily bag limit is 1 Canada goose and the possession limit is 2.

Louisiana: The season for Canada geese is closed.

Mississippi: In the:

(a) Sardis Zone—The season for Canada geese may extend for 30 days, 10 days of which must occur before December 15, 1988. The daily bag limit is 1 Canada goose and possession limit is 2.

(b) Remainder of the State—The season for Canada geese may be exceed 15 days. The daily bag limit is 1 Canada goose and the possession limit is 2.

Alabama: The daily bag limit is 2 Canada geese and the possession limit is 4.

Missouri, Illinois, Indiana, Kentucky and Tennessee Quota Zone Closures: When it has been determined that the quota of Canada geese allotted to the Southern Illinois Quota Zone, the Rend Lake Quota Zone in Illinois, the Swan

Lake Zone in Missouri, Posey County in Indiana, the Ballard and Henderson-Union Subzones in Kentucky and the Reelfoot Subzone in Tennessee will have been filled, the season for taking Canada geese in the respective area will be closed by the Director upon giving public notice through local information media at least 48 hours in advance of the time and date of closing, or by the State through State regulations with such notice and time (not less than 48 hours) as they deem necessary.

Shipping Restriction: In Illinois and Missouri and in the Kentucky counties of Ballard, Hickman, Fulton and Carlisle, geese may not be transported, shipped or delivered for transportation or shipment by common carrier, the Postal Service, or by any person except as the personal baggage of licensed waterfowl hunters, provided that no hunter shall possess or transport more than the legally-prescribed possession limit of geese. Geese possessed or transported by persons other than the taker must be labeled with the name and address of the taker and the date taken.

CENTRAL FLYWAY

The Central Flyway includes Colorado (east of the Continental Divide), Kansas, Montana (Blaine, Carbon, Fergus, Judith Basin, Stillwater, Sweetgrass, Wheatland and all counties east thereof), Nebraska, New Mexico (east of the Continental Divide except that the entire Jicarilla Apache Indian Reservation is in the Pacific Flyway), North Dakota, Oklahoma, South Dakota, Texas and Wyoming (east of the Continental Divide).

Ducks (including mergansers) and Coots

Outside Dates: October 8, 1988, through January 8, 1989.

Canvasbacks: The season on canvasbacks is closed.

Hunting Season: Seasons in the Low Plains Unit may include no more than 39 days. Seasons in the High Plains Mallard Management Unit may include no more than 51 days, provided that the last 12 days may start no earlier than December 10, 1988. The High Plains Unit, roughly defined as that portion of the Central Flyway which lies west of the 100th meridian, shall be described in State regulations.

States may split their seasons into 2 or, in lieu of zoning, 3 segments.

Daily Bag and Possession Limits: The daily bag limit is 3 ducks daily, including no more than 2 mallards, no more than 1 of which may be a female, 1 redhead, 1 hooded merganser, and 2 wood ducks. For pintails, the daily bag limit during the first 7 days of the hunting season is 1. During the last 9 days of the season, the daily bag limit is 2 male pintails. During the period between the first 7 days and the last 9 days, the season on pintails is closed. The possession limit is twice the daily bag limit, except that the possession limit for the female mallard is 1.

Daily bag and possession limits for coots are 15 and 30, respectively.

Zoning: Duck and coot hunting seasons may be selected independently in existing zones as described in the following States:

Montana (Central Flyway portion):

Experimental Zone 1. The counties of Bighorn, Blaine, Carbon, Daniels, Fergus, Garfield, Golden Valley, Judith Basin, McCone, Musselshell, Petroleum, Phillips, Richland, Roosevelt, Sheridan, Stillwater, Sweetgrass, Valley, Wheatland and Yellowstone.

Experimental Zone 2. The counties of Carter, Custer, Dawson, Fallon, Powder River, Prairie, Rosebud, Treasure and Wibaux.

Nebraska (Low Plains portion):

Zone 1. Keya Paha County east of U.S. Highway 183 and all of Boyd County including the adjacent waters of the Niobrara River.

Zone 2. The area bounded by designated highways and political boundaries starting on U.S. 73 at the State Line near Falls City; north to N-67; north through Nemaha to U.S. 73-75; north to U.S. 34; west to the Alvo Road; north to U.S. 6; northeast to N-63; north and west to U.S. 77; north to N-92; west to U.S. 81; south to N-66; west to N-14; south to I-80; west to U.S. 34; west to N-10; south to the State Line; west to U.S. 283; north to N-23; west to N-47; north to U.S. 30; east to N-14; north to N-52; northwesterly to N-91; west to U.S. 281; north to Wheeler County and including all of Wheeler and Garfield Counties and Loup County east of U.S. 183; east on N-70 from Wheeler County to N-14; south to N-39; southeast to N-22; east to U.S. 81; southeast to U.S 30; east to U.S. 73; north to N-51; east to the State Line; and south and west along the State Line to the point of beginning.

Zone 3. The area, excluding Zone 1, north of Zone 2.

Zone 4. The area south of Zone 2.

New Mexico:

Experimental Zone 1. The Central Flyway portion of New Mexico north of Interstate Highway 40 and U.S. Highway 54.

Experimental Zone 2. The remainder of the Central Flyway portion of New Mexico.

Oklahoma:

Zone 1. That portion of northwestern Oklahoma, except the Panhandle, bounded by the following highways: starting at the Texas-Oklahoma border, OK 33 to OK 47, OK 47 to U.S. 183, U.S. 183 to I-40, I-40 to U.S. 177, U.S. 177 to OK 33, OK 33 to I-35, I-35 to U.S. 60, U.S. 60 to U.S. 64, U.S. 64 to OK 132, and OK 132 to the Oklahoma-Kansas State line.

Zone 2. The remainder of the Low Plains.

South Dakota (Low Plains portions)

South Zone. Bon Homme, Yankton and Clay Counties south of S.D. Highway 50; Charles Mix County south and west of a line formed by S.D. Highway 50 from Douglas County to Geddes, Highways CFAS 6198 and FAS 6516 to Lake Andes, and S.D. Highway 50 to Bon Homme County; Gregory County; and Union County south and west of S.D. Highway 50 and Interstate Highway 29.

North Zone. The remainder of the Low Plains.

Wyoming (Central Flyway portion): In lieu of its previous four zones, Wyoming may split their season in the Central Flyway portion of the State into three segments of equal or unequal length.

Geese

Definitions: In the Central Flyway, "geese" includes all species of geese and brant, "dark geese" includes Canada and white-fronted and black brant, and "light geese" includes all others.

Outside Dates: October 1, 1988, through January 22, 1989, for dark geese and October 1, 1988, through February 14, 1989 (February 28, 1989, in New Mexico), for light geese.

Possession Limits: Goose possession limits are twice the daily bag limits (see exception for light geese in the Rio Grande Valley Unit of New Mexico).

Hunting Season: Seasons in States, and independently in described goose management units within States, may be as follows:

Colorado: No more than 95 days with a daily limit of 5 geese that may include no more than 2 dark geese.

Kansas: For dark geese, no more than 72 days with daily limits of 2 Canada geese or 1 Canada goose and 1 white-fronted goose through November 27 and no more than 1 Canada goose and 1 white-fronted goose during the remainder of the season.

For Light Goose Unit 1 (that area east of U.S. 75 and north of I-70), no more than 86 days with a daily limit of 5.

For Light Goose Unit 2 (the remainder of Kansas), no more than 86 days with a daily limit of 5.

Montana: No more than 95 days with daily limits of 2 dark geese and 3 light geese in Sheridan County and 3 dark geese and 3 light geese in the remainder

of the Central Flyway portion of the State.

Nebraska: For Dark Goose Unit 1 (Boyd, Cedar west of U.S. 81, Keya Paha east of U.S. 183, and Knox Counties), no more than 79 days with daily limits of 1 Canada goose and 1 white-fronted goose through November 12 and no more than 2 Canada geese or 1 Canada goose and 1 white-fronted goose for the remander of the season.

For Dark Goose Unit 2 (the remainder of the State east of the following highways starting at the South Dakota line; U.S. 183 to NE 2, NE 2 to U.S. 281, and U.S. 281 to Kansas), no more than 72 days with daily limits of 2 Canada geese or 1 Canada goose and 1 white-fronted goose through November 20 and nor more than 1 Canada goose and 1 white-fronted goose for the remainder of the season.

For Dark Goose Unit 3 (that part of the State west of Units 1 and 2), no more than 72 days with daily limits of 2 Canada geese or 1 Canada goose and 1 white-fronted goose through November 20 and no more than 1 Canada goose and 1 white-fronted goose for the remainder of the season.

For light geese, no more than 86 days with a daily limit of 5.

New Mexico: For dark geese, no more than 95 days with a daily limit of 2.

For light geese in the Rio Grande Valley Unit (the Central Flyway portion of New Mexico west of highways starting at the Texas line north of El Paso: U.S. 54 to U.S. 60, U.S. 60 to U.S. 285, and U.S. 285 to the Colorado line), no more than 107 days with a daily limit of 5 and a possession of 20.

For light geese in the remainder of the Central Flyway portion of New Mexico, no more than 95 days with a daily limit of 5.

North Dakota: For dark geese, no more than 72 days with a daily limits of 1 Canada goose and 1 white-fronted goose or 2 white-fronted geese through October 30 and no more than 2 dark geese during the remainder of the season.

For light geese, no more than 86 days with a daily limit of 5.

Oklahoma: For dark geese, no more than 72 days with a daily limit of 2 Canada geese or 1 Canada goose and 1 white-fronted goose.

For light geese, no more that 86 days with a daily limit of 5.

South Dakota: For dark geese in the Missouri River Unit (the Counties of Bon Homme, Brule, Buffalo, Campbell, Charles Mix, Corson east of SD Highway 65, Dewey, Gregory, Haakon north of Kirley Road and east of Plum Creek, Hughes, Hyde, Lyman north of Interstate, 90 and east of U.S. Highway 183, Potter, Stanley, Sully, Trip east of U.S. Highway 183, Walworth, and Yankton west of U.S. Highway 81), no more than 79 days with daily limits of 1 Canada goose and 1 white-fronted goose through November 12 and no more than 1 Canada geese or 1 Canada goose and 1 white-fronted goose for the remainder of the season.

For dark geese in the remainder of the State, no more than 72 days with a daily limit of 1 Canada goose and 1 white-fronted goose.

For light geese, no more than 86 days with a daily limit of 5.

Texas: West of U.S. 81, no more than 95 days with a daily limit of 5 geese which may include no more than 2 dark geese.

For dark geese east of U.S. 81, no more than 72 days with a daily limit of 1 Canada goose and 1 white-fronted goose.

For light geese east of U.S. 81, no more than 86 days with a daily limit of 5.

Wyoming: No more than 95 days with a daily limit of 2.

Tundra Swans

The following States may issue permits authorizing each permittee to take no more than one tundra swan, subject to guidelines in a current, approved management plan and general conditions that each State determine hunter participation and harvest, and specified conditions as follows:

Montana (Central Flyway portion): no more than 500 permits with the season dates concurrent with the season for taking geese.

North Dakota: no more than 1,000 permits with the season dates concurrent with the season for taking light geese.

South Dakota: no more than 500 permits with the season dates concurrent with the season for taking light geese.

PACIFIC FLYWAY

The Pacific Flyway includes Arizona, California, Colorado (west of the Continental Divide), Idaho, Montana (including and to the west of Hill, Chouteau, Cascade, Meagher and Park Counties), Nevada, New Mexico (the Jicarilla Apache Indian Reservation and west of the Continental Divide), Oregon, Utah, Washington and Wyoming (west of the Continental Divide including the Great Divide Basin).

Ducks, Coots, and Common Moorhens, and Common Snipe

Outside Dates: Between October 8, 1988, and January 8, 1989.

Hunting Seasons: Seasons may be split into two segments. Concurrent 59-day seasons on ducks (including mergansers), coots, common moorhens (gallinules) and common snipe may be selected except as subsequently noted. In the Oregon counties of Morrow and Umatilla and in Washington all areas lying east of the summit of the Cascade Mountains and east of the Big White Salmon River in Klickitat County, the seasons may be an additional 7 days.

Canvasback: The season on canvasbacks is closed.

Duck Limits: The basic daily bag limit is 4 ducks, including no more than 3 mallards, no more than 1 of which may be a female, and 2 redheads. For pintails, the daily bag limit during the first 7 days of the hunting season is 1. During the last 16 days of the season, the daily bag limit is 2 male pintails. During the period between the first 7 days and the last 16 days, the season on pintails is closed. The possession limit is twice the daily bag limit.

Coot and Common Moorhen (Gallinule) Limits: The daily bag and possession limit of coots and common moorhens is 25 singly or in the aggregate.

Common Snipe Limits: The daily bag and possession limit of common snipe is 8 and 16, respectively.

California—Waterfowl Zones: Season dates for the Colorado River Zone of California must coincide with season dates selected by Arizona. Season dates for the Northeastern and Southern Zones of California may differ from those in the remainder of the State.

Idaho—Duck Zones: Duck season dates for Zone 1 and Zone 2 may differ. Zone 1 includes all lands and waters within the Fort Hall Indian Reservation and Bannock County; Bingham County except that portion within the Blackfoot Reservoir drainage; and Power County east of State Highway 37 and State Highway 39. Zone 2 includes the remainder of the State.

Nevada—Clark County Waterfowl Zone: Season dates for Clark County may differ from those in the remainder of Nevada.

Colorado, Montana, New Mexico and Wyoming—Common Snipe: For States partially within the Flyway a 93-day season for common snipe may be selected to occur between September 1, 1988, and February 28, 1989, and need not be concurrent with the duck season.

Geese (including Brant)

Outside dates, season lengths and limits on geese (including brant): Seasons may be split into two segments. Between October 1, 1988, and January 22, 1989, a 93-day season on geese (except brant in Washington, Oregon

and California) may be selected, except as subsequently noted. The basic daily bag and possession limit is 6, provided that the daily bag limit includes no more than 3 white geese (snow, including blue, and Ross' geese) and 3 dark geese (all other species of geese). In Washington and Idaho, the daily bag and possession limits are 3 and 6 geese, respectively. Washington, Oregon and California may select an open season for brant with daily bag and possession limits of 2 and 4 brant, respectively. Brant seasons may not exceed 16-consecutive days in Washington and Oregon and 30-consecutive days in California.

Aleutian Canada goose closure: There will be no open season on Aleutian Canada geese. Emergency closures may be invoked for all Canada geese should Aleutian Canada goose distribution patterns or other circumstances justify such actions.

California, Oregon, Washington—Cackling Canada goose closure: There will be no open season on cackling Canada geese in California, Oregon and Washington.

California—Canada goose and dark goose closures: Three areas in California, described as follows, are restricted in the hunting of certain geese:

(1) In the counties of Del Norte and Humboldt there will be no open season for Canada geese.

(2) In the Sacramento Valley in that area bounded by a line beginning at Willows in Glenn County proceeding south on Interstate Highway 5 to the junction with Hahn Road north of Arbuckle in Colusa County; then easterly on Hahn Road and the Grimes-Arbuckle Road to Grimes on the Sacramento River; then southerly on the Sacramento River to the Tisdale By-pass; then easterly on the Tisdale By-pass to where it meets O'Banion Road; then easterly on O'Banion Road to State Highway 99; then northerly on State Highway 99 to its junction with the Gridley-Colusa Highway in Gridley in Butte County; then westerly on the Gridley-Colusa Highway to its junction with the River Road; then northerly on the River Road to the Princeton Ferry; then westerly across the Sacramento River to State Highway 45; then northerly on State Highway 45 to its junction with State Highway 162; then continuing northerly on State Highway 45–162 to Glenn; then westerly on State Highway 162 to the point of beginning in Willows, there will be no open season for Canada geese. In this area, the season on dark geese must end on or before November 30, 1988.

(3) In the San Joaquin Valley in that area bounded by a line beginning at Modesto in Stanislaus County proceeding west on State Highway 132 to the junction of Interstate Highway 5; then southerly on Interstate Highway 5 to the junction of State Highway 152 in Merced County; then easterly on State Highway 152 to the junction of State Highway 59; then northerly on State Highway 59 to the junction of State Highway 99 at Merced; then northerly and westerly on State Highway 99 to the point of beginning; the hunting season for Canada geese will close no later than November 23, 1988.

California (Northeastern Zone)—geese: In the Northeastern Zone of California the season may be from October 8, 1988, to January 8, 1989, except that white-fronted geese may be taken only during October 8 to November 1, 1988. Limits will be 3 geese per day and 6 in possession, of which not more than 1 white-fronted goose or 2 Canada geese shall be in the daily limit and not more than 2 white-fronted geese and 4 Canada geese shall be in possession.

California (Balance of the State Zone)—geese: In the Balance of the State Zone the season may be from October 30, 1988, through January 22, 1989, except that white-fronted geese may be taken only during October 30, 1988, to January 1, 1989. Limits shall be 3 geese per day and in possession, of which not more than 1 may be a dark goose. The dark goose limits may be expanded to 2 provided that they are Canada geese (except Aleutian and cackling Canada geese for which the season is closed).

Western Oregon: In those portions of Coos and Curry Counties lying west of U.S. Highway 101 and that portion of Western Oregon west and north of a line starting at Oregon-Washington State line on the Columbia River; south on Interstate Highway 5 to its junction with State Highway 22 at Salem; east on State Highway 22 to the Stayton cutoff; south on the Stayton cutoff through Stayton and straight south to the Santiam River; west (downstream) on the Santiam River to Interstate Highway 5; south on Interstate Highway 5 to State Highway 126 at Eugene; west on State Highway 126 and ending at the Oregon coast, except for designated areas, there shall be no open season on Canada geese. In the remainder of Western Oregon, the season and limits shall be the same as those for the Pacific Flyway, except the seasons in the designated area must end upon attainment of their individual quotas which collectively equal 210 dusky Canada geese. Hunting of Canada geese in those designated areas shall only be by hunters possessing a state-issued permit authorizing them to do so.

Oregon (Lake and Klamath Counties)—geese: In the Oregon counties of Lake and Klamath the season on white-fronted geese will not open before November 1.

Washington and Oregon (Columbia Basin Portions)—geese: In the Washington counties of Adams, Benton, Douglas, Franklin, Grant, Kittitas, Klickitat, Lincoln, Walla Walla, and Yakima, and in the Oregon counties of Gilliam, Morrow, Sherman, Umatilla, Union, Wallowa and Wasco, the goose season may be an additional 7 days.

Western Washington: In Clark, Cowlitz, Wahkiakum, and Pacific Counties, except for areas to be designated by the State, there shall be no open season on Canada geese. For designated areas the seasons must end upon attainment of individual quotas which collectively will equal 90 dusky Canada geese. Hunting of Canada geese in those designated areas shall only be by hunters possessing a state-issued permit authorizing them to do so.

Idaho, Oregon and Montana—Pacific Population of Canada geese: In that portion of Idaho lying west of the line formed by U.S. Highway 93 north from the Nevada border to Shoshone, thence northerly on Idaho State Highway 75 (formerly U.S. Highway 93) to Challis, thence northerly on U.S. Highway 93 to the Montana border (except Boundary, Bonner, Kootenai, Benewah, Shoshone, Latah, Nez Perce, Lewis, Clearwater and Idaho Counties); in the Oregon counties of Baker and Malheur; and in Montana (Pacific Flyway portion west of the Continental Divide), the daily bag and possession limits are 2 and 4 Canada geese, respectively; and the season for Canada geese may not extend beyond January 8, 1989.

Montana and Wyoming—Rocky Mountain Population of Canada Geese: In Montana (Pacific Flyway portion east of the Continental Divide) and Wyoming the season may not extend beyond January 8, 1989. In Lincoln, Sweetwater and Sublette Counties, Wyoming, the combined special sandhill crane-Canada goose seasons and the regular goose season shall not exceed 93 days.

Idaho, Colorado and Utah: In that portion of Idaho lying east of the line formed by U.S. Highway 93 north from the Nevada border to Shoshone, thence northerly on Idaho State Highway 75 (formerly U.S. Highway 93) to Challis, thence northerly on U.S. Highway 93 to the Montana border; in Colorado; and in Utah, except Washington County, the daily bag and possession limits are 2 and 4 Canada geese, respectively, and

the season for Canada geese may be no more than 86 days and may not extend beyond January 8, 1989.

Nevada: Nevada may designate season dates on geese in Clark County and in Elko County and that portion of White Pine County within Ruby Lake National Wildlife Refuge differing from those in the remainder of the State. In Clark County the season on Canada geese may be no more than 86 days. Except for Clark County the daily bag and possession limits are 2 and 4 Canada geese, respectively. In Clark County the daily bag and possession limits are 2 Canada geese.

Arizona, California, Utah and New Mexico: In California, the Colorado River Zone where the season must be the same as that selected by Arizona and the Southern Zone; in Arizona; in New Mexico; and in Washington County, Utah; the season for Canada geese may be no more than 86 days. The daily bag and possession limit is 2 Canada geese except in that portion of California Department of Fish and Game District 22 within the Southern Zone (i.e. Imperial Valley) where the daily bag and possession limits for Canada geese are 1 and 2, respectively.

Tundra Swans

In Utah, Nevada and Montana, an open season for tundra swans may be selected to the following conditions: (a) between October 1, 1988, and January 22, 1989, a 93-day season may be selected, and seasons may be split into two segments; (b) appropriate State agency must issue permits and obtain harvest and hunter participation data; (c) in Utah, no more than 2,500 permits may be issued, authorizing each permittee to take 1 tundra swan; (d) in Nevada, no more than 650 permits may be issued, authorizing each permittee to take 1 tundra swan in either Churchill, Lyon, or Pershing Counties; (e) in Montana, no more than 500 permits may be issued authorizing each permittee to take 1 tundra swan in either Teton, Cascade, Hill, Liberty, Toole or Pondera Counties.

Special Falconry Frameworks

Extended Seasons

Falconry is a permitted means of taking migratory game birds in any State meeting Federal falconry standards in 50 CFR 21.29(k). These States may select an extended season not exceeding 107 days for taking migratory game birds in accordance with the following:

Framework Dates

Seasons must fall between September 1, 1988 and March 10, 1989.

Daily Bag and Possession Limits

Falconry daily bag and possession limits for all permitted migratory game birds shall not exceed 3 and 6 birds, respectively, singly or in the aggregate, during both regular hunting seasons and extended falconry seasons.

Regulations Publication

Each State selecting the special season must inform the Service of the season dates and publish said regulations.

Regular Seasons

General hunting regulations, including seasons, hours, and limits, apply to falconry in each State listed in 50 CFR 21.29(k) which does not select an extended falconry season.

Note.—In no instance shall the total number of days in any combination of duck seasons (regular duck season, sea duck season, September seasons, or falconry season) exceed 107 days for a species in one geographical area. The extension of this framework to include the period September 1, 1988—March 10, 1989, is considered tentative, and will be evaluated in cooperation with States offering such extensions after a period of several years.

Date: August 9, 1988.

Susan Recce,

Acting Assistant Secretary for Fish and Wildlife and Parks.

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