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Friday
October 6, 1995

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WASHINGTON, DC

[Two Sessions]

WHEN: October 17 at 9:00 am and 1:30 pm

WHERE: Office of the Federal Register Conference Room, 800 North Capitol Street NW., Washington, DC (3 blocks north of Union Station Metro)

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Free Electronic Bulletin Board service for Public Law numbers, Federal Register finding aids, and a list of documents on public inspection is available on 202–275–1538 or 275–0920.

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Presidential Documents

Title 3—

The President

Proclamation 6830 of October 4, 1995

Energy Awareness Month, 1995

By the President of the United States of America

A Proclamation

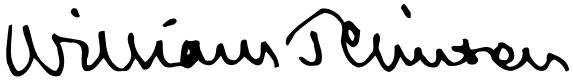
Although we tend to focus on energy issues only in times of crisis, Americans should not underestimate the daily impact of a clean, safe, affordable energy supply on maintaining our standard of living, protecting the environment, and ensuring our national defense. In the past 3 decades alone, disruptions in global oil markets and dramatic price shocks have caused international strife and economic recession. Energy choices affect air and water pollution; nuclear, toxic, and other waste disposal present potential hazards; and energy use can influence our precious wilderness and natural ecosystems.

As we observe Energy Awareness Month, 1995, this year's theme, ''Energy Fuels Our Future,'' is a powerful reminder of the need to build a strong foundation of sustainable energy policies that will benefit the generations to come. We can be proud of the United States' efforts toward this end. In every critical sector of society—commercial and residential development, transportation, industry, utility management, and government—we have improved efficiency and reduced the environmental impact of energy production and consumption.

Our challenge today is to continue this work, and my Administration remains committed to the responsible use of existing resources and the progress of innovative technology. We have many objectives—enhancing the competitiveness of our Nation's oil producers, expanding the role of domestically produced natural gas, encouraging the development of renewable energy resources, minimizing the environmental impact of coal use, and supervising the safe contribution of nuclear energy. As we seek to strengthen our economy and ease the burden of energy use on the global environment, let us work together toward these vital goals.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim October 1995 as ''Energy Awareness Month.'' I call upon government officials, educators, and all the people of the United States to observe this month with appropriate activities recognizing the central importance of energy use in our lives and to the future of our world.

IN WITNESS WHEREOF, I have hereunto set my hand this fourth day of October, in the year of our Lord nineteen hundred and ninety-five, and of the Independence of the United States of America the two hundred and twentieth.



[FR Doc. 95–25073
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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

Cooperative State Research, Education, and Extension Service

7 CFR Part 8

4–H Club Name and Emblem

AGENCY: Cooperative State Research, Education, and Extension Service, USDA.

ACTION: Final rule.

SUMMARY: The Cooperative State Research, Education, and Extension Service (CSREES) is amending 7 CFR part 8 to reflect the abolishment of the Extension Service and the establishment of the Cooperative State Research, Education, and Extension Service in the recent Department of Agriculture reorganization.

EFFECTIVE DATE: October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Louise Ebaugh at (202) 401–5024.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Pursuant to Public Law 103–354, the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, the Secretary of Agriculture issued Secretary's Memorandum 1010–1, Reorganization of the Department of Agriculture, on October 20, 1994. That memorandum orders the abolishment of the Extension Service and the establishment of the Cooperative State Research, Education, and Extension Service which assumes the function previously performed by the Extension Service. This amendment to 7 CFR part 8 is necessary to bring agency regulations into alignment with the departmental reorganization.

List of Subjects in 7 CFR Part 8

Agriculture, 4–H Club, Signs and symbols.

For reasons set out in the preamble, title 7, subtitle A, part 8 is amended by removing all references to ''Extension Service'' and adding ''Cooperative State Research, Education, and Extension Service'' in its place everywhere it appears.

Done at Washington, D.C. this 29th day of September 1995.

William D. Carlson,

Acting Administrator, Cooperative State Research, Education, and Extension Service.

[FR Doc. 95–24819 Filed 10–5–95; 8:45 am]

BILLING CODE 3410–22–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 94–AWP–8]

Establishment of Class D Airspace; Bullhead City, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class D airspace at Bullhead City, AZ. An Airport Traffic Control Tower has been commissioned at Laughlin/Bullhead International Airport. This action will provide adequate Class D airspace for instrument flight rules (IFR) operations and required two-way radio communications at Laughlin/Bullhead International Airport.

EFFECTIVE DATE: 0901 UTC, January 4, 1996.

FOR FURTHER INFORMATION CONTACT: Scott Speer, System Management Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90261, telephone (310) 725–6533.

SUPPLEMENTARY INFORMATION:

History

On May 11, 1994, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish Class D airspace at Bullhead City, AZ (59 FR 24384). A Standard Instrument Approach Procedure (SIAP) has been developed for the Laughlin/Bullhead International Airport at Bullhead City, AZ. Also, an Airport Traffic Control Tower has been commissioned at Laughlin/Bullhead International Airport. This action will provide adequate Class D airspace for IFR operations and required two-way radio communications at Laughlin/Bullhead International Airport.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received. Class D airspace designations are published in Paragraph 5000 of FAA Order 7400.9C, dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulation establishes a Class D airspace area at Laughlin/Bullhead International Airport, Bullhead City, AZ. This action will provide adequate Class D airspace for IFR operations and required two-way radio communications at Laughlin/Bullhead International Airport, Bullhead City, AZ.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g) 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AWP AZ D Bullhead City, AZ [New]
Laughlin/Bullhead International Airport, AZ
(lat. 35°08′50″N, long. 114°33′32″W)

That airspace extending upward from the surface to and including 2,500 feet AGL within a 4.2 mile radius of the Laughlin/Bullhead International Airport; excluding that airspace west of a line 1.8 miles west of and parallel to the north/south runway. This Class D airspace is effective during the specific dates and times established in advanced by a Notice to Airmen. The effective date and times will thereafter be continuously published in the Airport/Facility Directory.

Issued in Los Angeles, California, on September 26, 1995.

James H. Snow,

Acting Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 95–24944 Filed 10–5–95; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 10, 19, 54, 125, 141, and 144

[T. D. 95–81]

RIN 1515–AB80

Replacement of CF 7505 and CF 7506 by CF 7501

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations to eliminate references to Customs Form (CF) 7505, Warehouse Withdrawal for Consumption, and CF 7506, Warehouse Withdrawal Conditionally Free of Duty, to reflect Customs elimination of the two forms. The CF 7501, Entry Summary, will be used in lieu of the eliminated forms. The elimination of the CF 7505 and CF 7506 will streamline documentation requirements for Customs entry processing.

EFFECTIVE DATE: October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Raymond Janiszewski, Office of Trade Compliance, (202) 927–0380.

SUPPLEMENTARY INFORMATION:

Background

Previously, Customs Form (CF) 7505, Warehouse Withdrawal for Consumption, was the form used to make warehouse withdrawals for consumption. CF 7506, Warehouse Withdrawal Conditionally Free of Duty and Permit, was the form used to make warehouse withdrawals for merchandise conditionally free of duty. Customs has decided that CF 7505 and CF 7506 are unnecessary, because all the required information is given on the CF 7501.

As a result of the elimination of CF 7505 and CF 7506, the paperwork burden on the trade is reduced, and the documentation required for Customs processing is streamlined, because only one document (rather than three) is now required.

Inapplicablity of Public Notice and Comment Requirements and Delayed Effective Date Requirements

Inasmuch as these amendments merely substitute one Customs form for two other Customs forms reflecting the elimination of two forms, pursuant to 5 U.S.C. 553(a)(2) and (b)(B), good cause exists for dispensing with notice and public procedure thereon as unnecessary. For the same reason, good cause exists for dispensing with the requirement for a delayed effective date, under 5 U.S.C. 553(a)(2) and (d)(3).

Regulatory Flexibility Act and Executive Order 12866

Based on the supplementary information set forth above, it is certified that the amendments will not have a significant economic impact on a substantial number of small entities. Accordingly, the amendments are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 or 604.

This document does not meet the criteria for a ‘‘significant regulatory action’’ as specified in Executive Order 12866.

Drafting Information

The principal author of this document was Janet L. Johnson, Regulations Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects

Part 10

Caribbean Basin initiative, Customs duties and inspection, Exports, Reporting and recordkeeping requirements.

Part 19

Customs duties and inspection, Exports, Freight, Reporting and recordkeeping requirements, Surety bonds, Warehouses, Wheat.

Part 54

Customs duties and inspection, Metals, Reporting and recordkeeping requirements.

Part 125

Customs duties and inspection, Freight, Government contracts, Harbors, Reporting and recordkeeping requirements.

Part 141

Customs duties and inspection, Reporting and recordkeeping requirements.

Part 144

Customs duties and inspection, Reporting and recordkeeping requirements, Warehouses.

Amendments to the Regulations

For the reasons set forth in the preamble, parts 10, 19, 54, 125, 141, and 144 of the Customs Regulations (19 CFR 10, 19, 54, 125, 141, and 144) are amended as set forth below.

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

1. The general authority citation and specific relevant authority citations for Part 10 continue to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1321, 1481, 1484, 1498, 1508, 1623, 1624.

* * * * *

Section 10.59 also issued under 19 U.S.C. 1309, 1317;

Sections 10.61, 10.62, 10.63, 10.64, 10.64a also issued under 19 U.S.C. 1309;

Section 10.62a, 10.65 also issued under 19 U.S.C. 1309, 1317, 1555, 1556, 1557, 1646a;

* * * * *

Sections 10.80, 10.81, 10.82, 10.83 also issued under 19 U.S.C. 1313(e) and (i);

* * * * *

§ 10.59 [Amended]

2. Section 10.59(e) is amended by removing the reference ‘‘Customs Form 7506’’ and by adding ‘‘Customs Form 7501’’ in its place.

§ 10.60 [Amended]

3. Section 10.60(a) is amended by removing the words ''Customs Form 7506 (Warehouse Withdrawal Conditionally Free of Duty)'' and by adding ''Customs Form 7501'' in its place.

4. Section 10.60(d) is amended by removing the words ''Customs Form 7506'' in each place they appear and by adding ''Customs Form 7501'' in their place.

§ 10.61 [Amended]

5. Section 10.61 is amended by removing the reference ''Customs Form 7506'' and by adding ''Customs Form 7501'' in its place.

§ 10.62 [Amended]

6. Section 10.62(a) introductory text and (b) are amended by removing the reference ''Customs Form 7506'' wherever it appears and by adding ''Customs Form 7501'' in its place.

§ 10.62a [Amended]

7. Section 10.62a (a) and (b) are amended by removing the reference ''Customs Form 7506'' wherever it appears and by adding ''Customs Form 7501'' in its place.

§ 10.80 [Amended]

8. Section 10.80 is amended by removing the reference ''Customs Form 7506'' wherever it appears and by adding ''Customs Form 7501'' in its place.

§ 10.81 [Amended]

9. Section 10.81(b) is amended by removing the words ''with Customs Form 7506 attached to show'' and by adding the words ''which shall show'' in their place.

§ 10.102 [Amended]

10. Section 10.102(b) introductory text is amended by removing the words ''or 7506''.

PART 19—CUSTOMS WAREHOUSES, CONTAINER STATIONS AND CONTROL OF MERCHANDISE THEREIN

1. The general authority citation and the specific relevant authority citations for Part 19 continue to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202, (General Note 20, Harmonized Tariff Schedule of the United States), 1624.

* * * * *

Section 19.6 also issued under 19 U.S.C. 1555;

* * * * *

Section 19.11 also issued under 19 U.S.C. 1556, 1562;

Section 19.15 also issued under 19 U. S.C. 1311;

* * * * *

§ 19.6 [Amended]

2. Section 19.6(d)(2) is amended by removing the words ''Customs Form 7506 or 7505, as appropriate,'' and by adding ''Customs Form 7501'' in their place.

3. Section 19.6(d)(4) is amended by removing the reference ''Customs Form 7506'' and by adding ''Customs Form 7501'' in its place.

§ 19.11 [Amended]

4. Section 19.11(g) is amended by removing the reference ''Customs Form 7505'' and by adding ''Customs Form 7501'' in its place.

§ 19.15 [Amended]

5. Section 19.15(b) and (d) are amended by removing the reference ''Customs Form 7505'' where it appears and by adding ''Customs Form 7501'' in its place.

PART 54—CERTAIN IMPORTATIONS TEMPORARILY FREE OF DUTY

1. The general authority citation for Part 54 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Section XV, Note 5, Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624.

§ 54.6 [Amended]

2. Section 54.6(b) is amended by removing the reference ''Customs Form 7506'' and by adding ''Customs Form 7501'' in its place.

PART 125—CARTAGE AND LIGHTERAGE OF MERCHANDISE

1. The general authority citation for Part 125 and the specific relevant authority continue to read as follows:

Authority: 19 U.S.C. 66, 1565 and 1624.

* * * * *

Section 125.31 also issued under 5 U.S.C. 301; 19 U.S.C. 1311, 1312, 1484, 1555, 1556, 1557, 1623, and 1646a.

* * * * *

§ 125.31 [Amended]

2. Section 125.31 is amended by removing paragraphs (c) and (d) and by redesignating paragraph (e) as paragraph (c).

PART 141—ENTRY OF MERCHANDISE

1. The general authority citation for Part 141 continues to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

* * * * *

§ 141.61 [Amended]

2. Section 141.61(a)(2) is amended by removing the words ''the warehouse withdrawal for consumption, Customs Form 7505, or''.

3. Section 141.61(e)(1)(i)(A) is amended by removing the words ''; the withdrawal form, Customs Form 7505 or 7506, in the space provided''.

4. Section 141.61(e)(1)(ii)(B) is amended by removing the words ''and at the top of columns 3, 4, and 5 of Customs Forms 7505 and 7506,''.

5. Section 141.61(e)(1)(ii)(C) is amended by removing the sentence ''The charges shall be listed on Customs Forms 7505 and 7506 in Column 4 immediately below the HTSUS reporting numbers.''.

6. Section 141.61(f)(2)(i) is amended by removing the words ''and in the same general location as Customs Forms 7505, 7506''.

§ 141.68 [Amended]

7. Section 141.68(g)(1) and (g) concluding text are amended by removing the reference ''Customs Form 7505'' in each place it appears and by adding ''Customs Form 7501'' in its place.

PART 144—WAREHOUSE AND REWAREHOUSE ENTRIES AND WITHDRAWALS

1. The general authority citation for Part 144 is revised to read and the relevant specific authority continues to read as follows:

Authority: 19 U.S.C. 66, 1484, 1557, 1559, 1624.

* * * * *

Section 144.37 also issued under 19 U.S.C. 1555, 1562.

2. Section 144.22 is amended by removing paragraph (c) and revising paragraph (a) to read as follows:

§ 144.22 Endorsement of transfer on withdrawal form.

* * * * *

(a) Customs Form 7501 for:

(i) A duty paid warehouse withdrawal for consumption;

(ii) Withdrawal with no duty payment (diplomatic use);

(iii) Merchandise to be withdrawn as vessel or aircraft supplies and equipment under § 10.60 of this chapter or other conditionally free merchandise;

* * * * *

§ 144.37 [Amended]

3. Section 144.37(a) is amended by:

a. removing the words ''Customs Form 7506 (Warehouse Withdrawal Conditionally Free of Duty, and Permit)'' in the first sentence and by

adding ''Customs Form 7501'' in its place;

b. removing the reference ''Customs Form 7506'' in the second sentence and adding ''Customs Form 7501'' in its place; and

c. removing the number ''7506'' in the third sentence and replacing it with ''7501''.

§ 144.38 [Amended]

4. Section 144.38(a) is amended by removing the words ''Customs Form 7505 (Warehouse Withdrawal for Consumption-Duty Paid)'' and by adding ''Customs Form 7501'' in their place.

5. Section 144.38(e) is amended by removing the words ''Customs Form 7505–A'' and by adding ''Customs Form 7501'' in their place.

Dated: September 28, 1995.

George J. Weise,

Commissioner of Customs.

Approved:

Richard Newcomb,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 95–24702 Filed 10–5–95; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

24 CFR Part 291

[Docket No. FR–3814–C–02]

RIN 2502–AG42

Sale of HUD-Held Single Family Mortgages; Correction

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Interim rule; correction.

SUMMARY: This document corrects an interim rule that HUD published in the Federal Register on August 31, 1995 (60 FR 45331) regarding the sale of HUD-held single family mortgages. The August 31, 1995 interim rule inadvertently described several categories of ineligible bidders. However, HUD intended the rule to contain only one category of ineligible bidders—individuals or entities debarred from doing business with HUD. This correction will broaden the category of eligible bidders in HUD's single family mortgage sales, excluding only those individuals or entities that have been debarred from doing business with HUD.

DATES: The dates listed in the August 31, 1995 interim rule remain unchanged.

FOR FURTHER INFORMATION CONTACT: Joseph Bates, Director, Single Family Servicing, Office of Housing, Room 9178, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, D.C. 20410, telephone (202) 708–1672. Hearing- or speech-impaired individuals may call the TDD number (202) 708–4594. (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: HUD published an interim rule to establish policies and procedures for the sale of HUD-held single family mortgages on August 31, 1995 (60 FR 45331). The interim rule provided that individuals or entities would be ineligible to bid if they fell into one of the following three categories: They are on HUD's most recent ''Consolidated List of Debarred, Suspended or Ineligible Contractors and Grantees,'' they are on probation or under a limited denial of participation, or they are subject to a withdrawal of approval or other sanctions. However, immediately before the interim rule was published, HUD determined that it would exclude from participation only those individuals or entities that had been debarred from doing business with HUD. HUD inadvertently failed to change the rule language to reflect this determination.

Therefore, this document corrects the preamble language of the interim rule and § 291.303 of the rule text by removing the descriptions of several categories of ineligible bidders and replacing them with one category of ineligible bidders, individuals or entities debarred from doing business with HUD. This correction will broaden the category of eligible bidders in HUD's single family mortgage sales, excluding only those individuals or entities that have been debarred from doing business with HUD.

Accordingly, FR Doc. 95–21449, an interim rule published in the Federal Register on August 31, 1995 (60 FR 45331) is corrected as follows:

1. On page 45332, in the preamble, in the second column, in the fourth paragraph under the heading ''Sales Policy,'' the last sentence, which begins ''In addition, * * *'' is corrected to read as follows:

SUPPLEMENTARY INFORMATION:

* * * * *

Sales Policy

* * * * *

* * * In addition, parties who are currently debarred pursuant to 24 CFR part 24, are ineligible to bid, either as an individual or participant, for any of the loan pools.

* * * * *

2. On page 45334, in column one, § 291.303 is corrected to read as follows:

§ 291.303 Eligible bidders.

HUD will provide information on the eligibility of bidders in the Bid Package, a Notice in the Federal Register, or other means, at the Secretary's full discretion. However, an individual, partnership, corporation, or other legal entity will not be eligible to bid for any loan pool, either as an individual or a participant, if at the time of the sale, that individual or entity is debarred from doing business with HUD pursuant to 24 CFR part 24.

Dated: September 29, 1995.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 95–24905 Filed 10–5–95; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–95–061]

RIN 2115–AE46

Special Local Regulations; City of Miami, FL

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Special Local Regulations are being adopted for the 1995 Columbus Day Cruising Regatta. The event will be held on October 7–8, 1995, from 9 a.m. EDT (Eastern Daylight Time) until 5 p.m. EDT on the seventh and from 9 a.m. EDT until 6 p.m. EDT on the eighth. These regulations are needed to provide for the safety of life on navigable waters during the event.

EFFECTIVE DATES: These regulations are effective on October 7, 1995, at 8:30 a.m. EDT and terminate on October 8, 1995, at 6:30 p.m. EDT.

FOR FURTHER INFORMATION CONTACT: QMC T.E. Kjerulff, USCG Group Miami, Florida at (305) 535–4448.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking has not been published for these regulations. The permit application was not received until August 28, 1995. Following

normal rulemaking procedures would have been impracticable, as there was insufficient time to publish proposed rule in advance of the event or to provide for a delayed effective date.

Drafting Information

The drafters of these regulations are LTJG Julia Diaz, project attorney, Seventh Coast Guard District Legal Office, and QMC T. Kjerulff, project officer, USCG Group Miami.

Discussion of Regulations

The 1995 Columbus Day Cruising Regatta is a sailboat race taking place on Biscayne Bay in the vicinity of Dinner Key Channel to the East Featherbed Bank. The event is a two-day race involving approximately six hundred 20 to 70 foot single and multi-hull sailing vessels with an additional 3,000 spectator craft expected to view the race. The significant amount of participating sailing vessels with the numerous spectator craft in the area will create an extra or unusual hazard in the navigable waterways.

Regulatory Evaluation

These regulations are not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this action to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. Entry into the regulated area is prohibited for only 9 hours each day of the event.

Since the impact of this action is expected to be minimal, the Coast Guard certified that it will not have a significant economic impact on a substantial number of small entities.

Environmental Assessment

The Coast Guard has considered the environmental impact of this action consistent with Section 2.B. of Commandant Instruction M16475.1B. In accordance with that section, this action has been environmentally assessed (EA completed), and the Coast Guard has determined that it will not significantly affect the quality of the human environment. An environmental assessment and finding of no significant impact have been prepared and are available for inspection and copying. As a condition to the permit, the applicant is required to educate the operators of spectator craft and parade participants regarding the possible presence of manatees and the appropriate precautions to take if the animals are sighted.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, waterways.

Temporary Regulations

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations, is amended as follows:

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233, 49 CFR 1.46 and CFR 100.35.

2. A temporary § 100.35–07–060 is added to read as follows:

§ 100.35–07–060 Key West Super Boat Race.

(a) *Regulated area.* All navigable waters within a line drawn through the following points:

Latitude 25°31.3′ N, approximately at Featherbed Bank Light #3 (LLNR 41340).

Datum: NAD 1983.

(b) *Special local regulations.* (1) Entry into the regulated area is prohibited unless authorized by the Patrol Commander.

(2) All vessels in the regulated area will follow the directions of the Patrol Commander and will proceed at no more than 5 MPH when passing through the regulated area.

(3) A succession of not fewer than 5 short whistle or horn blasts from a patrol vessel will be the signal for any non-participating vessel to stop immediately. The display of an orange distress smoke signal from a patrol vessel will be the signal for any and all vessels to stop immediately.

(c) *Effective Dates:* This section is effective on October 7, 1995, at 8:30 a.m. EDT and terminate on October 8, 1995, at 6:30 p.m. EDT.

Dated: September 22, 1995.

Roger T. Rufe, Jr.,

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

[FR Doc. 95–24919 Filed 10–5–95; 8:45 am]

BILLING CODE 4910–14–M

33 CFR Part 100

[CGD07–95–060]

Special Local Regulations; Key West Super Boat Race

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Special local regulations are being adopted for the Key West Super Boat Race sponsored by Super Boat Racing, Inc. This event will be held on November 8 and 12, 1995, between 10 a.m. and 4 p.m. EST (Eastern Standard Time). The regulations are needed to provide for the safety of life on navigable waters during the event.

EFFECTIVE DATES: These regulations are effective from 10 a.m. to 4 p.m. on November 8 and November 12, 1995.

FOR FURTHER INFORMATION CONTACT: QMC Hitchcock, project officer, USCG Group Key West, (305) 292–8727.

SUPPLEMENTARY INFORMATION: In accordance with 5 USC 553, a notice of proposed rulemaking has not been published for these regulations and good cause exists for making them effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impractical, as there was not sufficient time remaining to publish proposed rules in advance of the event or to provide for a delayed effective date.

Drafting Information

The drafters of this regulation are QMC R. C. Kent, project officer, USCG Group Key West, and LTJG Julia Diaz, project attorney, Seventh Coast District Legal Office.

Discussion of Regulations

Approximately 50 power boats are expected to participate in the Key West Super Boat Race, with 100 spectator craft expected. The power boats will be competing at high speeds and operating in close proximity to each other and to spectator craft, creating an extra or unusual hazard in the navigable waters.

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Evaluation

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not

require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this regulation to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. Entry into the regulated area is prohibited for only 6 hours on the day of the event.

Since the impact of this regulation is expected to be minimal, the Coast Guard certifies that it will not have a significant economic impact on a substantial number of small entities.

Federalism

This action has been analyzed in accordance with the principals and criteria contained in Executive Order 12612, and it has been determined that this rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assignment.

Environmental Assessment

The Coast Guard considered the environmental impact of this action consistent with Section 2.B. of Commandant Instruction M16475.1B. In accordance with that section, this action has been environmentally assessed (EA completed), and the Coast Guard has determined that it will not significantly affect the quality of the human environment. An environmental assessment and finding of no significant impact have been prepared and are available for inspection and copying.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water, Reporting and recordkeeping requirements, Waterways.

Final Regulations

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations, is amended as follows:

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary section 100.35–07–061 is added to read as follows:

§ 100.35–07–061 City of Miami, FL.

(a) *Regulated Area.* (1) The regulated area consists of all navigable waters on Biscayne Bay south of Rickenbacker Causeway and north from

(1) 24–33.65N, 081–48.47W; thence to,
(2) 24–33.95N, 081–48.30W; thence to,
(3) 24–34.05N, 081–48.45W; thence to,
(4) 24–33.58N, 081–48.70W; thence to,
(5) 24–31.18N, 081–51.10W; thence to,
(6) 24–31.18N, 081–48.88W; thence to,
(7) 24–32.94N, 081–48.82W.

(Datum: NAD 1983)

(b) *Special Local Regulations.* (1) Entry into the regulated area, by other than event participants, is prohibited unless otherwise authorized by the patrol commander.

(2) A succession of not less than 5 short whistle or horn blasts from a patrol vessel will be the signal for any non-participating vessel to take immediate steps to avoid collision. The display of a red distress flare from a patrol vessel will be a signal for any and all vessels to stop immediately.

(c) *Effective Dates.* This section is effective from 10 a.m. to 4 p.m. on November 8 and November 12, 1995.

Dated: September 13, 1995.

Roger T. Rufe, Jr.,

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

[FR Doc. 95–24918 Filed 10–5–95; 8:45 am]

BILLING CODE 4910–14–M

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33 CFR Part 117

[CGD09–95–023]

RIN–2115–AE47

Drawbridge Operation Regulations, Chicago River, IL

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard amends the operating regulations governing the drawbridges owned and operated by the City of Chicago over the Chicago River system. This final rule establishes the times when, and the conditions under which, the bridges need to open for the passage of commercial and recreational vessels, and requires advance notice of a recreational vessel's time of intended passage through the bridges. The rule allows additional drawbridge openings for flotillas of five or more recreational vessels. The regulations have one set of rules for the period of high vessel activity, from April 1 through November 30, and other rules for the remainder of the year. Further, certain bridges on the North Branch of the Chicago River have been deleted from the previous permanent rule because they no longer exist or are no longer in the route of commercial or recreational vessels.

The changes are being made in response to a request by the City of Chicago to reduce the number of required bridge openings. That request was premised on the unique situation in Chicago, where 26 bridges across the Chicago River and its North and South Branches in the very heart of the City. As a result, City officials asserted that drawbridge openings in Chicago are more numerous than in any other major city in the United States and have a correspondingly great impact on vehicular traffic. This action accommodates the needs of vehicle traffic while providing for the reasonable needs of navigation.

EFFECTIVE DATE: This rule is effective on November 19, 1995.

ADDRESSES: Documents referenced in this preamble are available for inspection and copying at the office of the Commander (obr), Ninth Coast Guard District, Room 2083, 1240 East Ninth Street, Cleveland, Ohio 44199–2060, between 6:30 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (216) 522–3993.

FOR FURTHER INFORMATION CONTACT: Ms. Carolyn Malone, Bridge Branch, Ninth Coast Guard District, (216) 522–3993.

SUPPLEMENTARY INFORMATION:

Regulatory History

A. Overview

The final rule that is published today is the culmination of over two years of analysis by the Coast Guard concerning what restrictions, if any, should be applicable to the opening of drawbridges in downtown Chicago. This has proven to be a highly contentious issue, and the task of arriving at a final rule has been difficult. During the past two years, the Coast Guard has sought and received public comments on 10 separate occasions (7 requests for comments on deviations, 1 request for comments on the regulatory negotiation process, and 2 requests for comments on Notices of Proposed Rulemaking). During this time, the Coast Guard also has conducted three public hearings, and has attempted to establish new rules during the course of what proved to be an unsuccessful negotiated rulemaking proceeding.

As discussed below, Chicago presents unique drawbridge problems since there are 26 drawbridges over the Chicago River in the heart of the City's commercial district. Every time the bridges are required to open, the flow of vehicular and pedestrian traffic is interrupted. On the other hand, sailboat owners who sail their boats on Lake Michigan historically have stored their boats during the winter at yards located along the river, and the transits to and

from these yards require periodic openings of the bridges. These transits to and from winter storage are commonly referred to as the Spring ''Breakout'' and Fall ''Return.'' During the Spring Breakout in April, May, and early June, boats travel down the Chicago River to seasonal moorings on Lake Michigan. At the end of the boating season in late September, October, and November, the boats travel back up the river for off-season storage; this is the Fall Return. Thus, there are substantial numbers of sailboats traveling the river between the yards and Lake Michigan during the Spring and Fall seasons. In addition, in-season repair work at the boatyards necessitates transiting the river. Restricting the times at which drawbridges can be required to open potentially impinges on the ability of sailboat owners to traverse the Chicago River between the boatyards and Lake Michigan. On the other hand, not restricting the times at which drawbridges can be required to open potentially impinges upon vehicular traffic crossing the bridges at such times.

The governing statute concerning drawbridge rules is clear. It imposes a duty on all persons ''owning, operating, and tending the drawbridges built * * * across the navigable rivers * * * of the United States, to open, or cause to be opened, the draws of such bridges * * * under such rules and regulations as in the opinion of the Secretary of Transportation the public interests require to govern the opening of drawbridges for the passage of vessels.'' (33 U.S.C. 499.) The Secretary of Transportation has delegated this authority to the Commandant, U.S. Coast Guard. The authority has been delegated further to the cognizant Coast Guard District Commander.

In 1988, the Congress redefined the focus of the statute by directing for the first time that, ''any rules and regulations made in pursuance of this section shall, to the extent practical and feasible, provide for regularly scheduled openings of drawbridges during seasons of the year and during times of the day, when scheduled openings would help reduce motor vehicle delays and congestion on roads and highways linked by drawbridges.'' Pub. L. No. 100–448, 102 Stat. 1846.

The balancing of interests between the boaters and boatyards in Chicago on the one hand, and the bridge owners and users, on the other, is the heart of the Chicago drawbridge controversy. It is obvious from the history of these proceedings and the litigation they have spawned that the wishes of the City, its citizens, the boaters, and the boatyards diverge greatly and cannot all be accommodated fully. As a consequence, the Coast Guard has conducted an exhaustive review of the extensive record before it and has independently balanced all of the competing concerns in determining what rule best serves the public interest consistent with the drawbridge statute and the 1988 amendment to it. The Coast Guard believes that the rule published today fully satisfies the requirements of that law and the public interest by ensuring the drawbridges in Chicago are opened under a schedule that allows reasonable navigation opportunities for the passage of vessels while also reducing motor vehicle traffic delays and congestion on Chicago's roads and highways to the extent practical and feasible.

B. History of the Proceeding

Since 1976, the regulations for the operation of the bridges on the Chicago River have provided for ''on-demand'' openings seven days a week, except during rush hours on Mondays through Fridays.

This regulation is referred to in this preamble as the ''1976 Rule.'' The 1976 Rule is a reference point for basic on-demand status. The regulatory language for temporary deviations is taken from the 1984 reorganization of 33 CFR Part 117.

1. The 1993 and 1994 Temporary Deviations

The provisions of 33 CFR 117.43 for many years have allowed a Chicago District Commander to authorize temporary deviations to regulations for no more than 90 days in order to evaluate suggested changes to drawbridge regulations. Notice of a temporary deviation is to be published in the Federal Register.

On May 12, 1993, the Coast Guard published a temporary deviation from the 1976 Rule to allow the City of Chicago to limit weekday openings for recreational vessels (58 Fed. Reg. 27933). The temporary deviation was effective from April 26, to May 31, 1993. It was implemented to evaluate the usefulness of requiring flotillas, in response to a request by the City of Chicago that claimed it was unduly burdensome to open bridges for a single vessel and that sought a schedule that would have restricted openings to Saturdays and Sundays. Discussions with the Coast Guard resulted in the consideration of flotilla requirements for the first time. Specifically, the City proposed a temporary deviation that provided for bridge openings conditioned upon receipt of 24-hour notice on Saturdays and Sundays from 6 a.m. to 7 p.m. for organized flotillas of 5 to 25 vessels, and on Tuesday and Thursday evenings from 6:30 p.m. until passage was completed for similarly-sized flotillas.

After discussions with the City and with boating interests, the Coast Guard adopted a schedule for the Spring, 1993 season which required bridges to open on twenty-four hours notice for flotillas of 5 to 25 vessels on Saturdays and Sundays during daylight hours and on Tuesday and Thursday evenings for flotillas of the same size (*Id.* at 27934). The Coast Guard noted that traditionally it had not specified flotilla requirements, but that such an approach might be appropriate in the context of Chicago, and that the temporary deviation would ''provide an evaluation period which will provide the Coast Guard a valuable test of the reasonableness of such a regulatory structure'' (*Id.*). On June 16, a second temporary deviation was published covering the period from June 1 to July 31, 1993 (58 Fed. Reg. 33191). This temporary deviation implemented a schedule which provided more daylight hours for passage. Many comments to the Coast Guard concerning the previous deviation had questioned the safety of evening passages and large flotilla trips, and the possibility of the City making greater efforts to shorten trip time. This temporary deviation expanded the temporary rules to cover Wednesday evenings in addition to Tuesday and Thursday evenings. It also established that vessels returning for necessary repairs and service shall give ''advance notice'' and be passed through with no flotilla requirement for inbound or outbound trips.

On August 12, a third temporary deviation was published which covered the period from August 1 to September 29, 1993 (58 FR 42856). This announcement solicited more information on the comments received during the two previous deviations which had indicated concern for safety of night trips and flotilla requirements. Schedule changes resulting from this deviation afforded more daylight hours for transit and eliminated flotilla sizes. A Wednesday morning opening at 11:00 a.m. was added to supplement the evening opening for that day. Openings continued to be provided on Tuesday and Thursday evenings, with 2 openings available on each of the weekend days.

On October 21, the Coast Guard implemented a fourth temporary deviation covering the period from October 1 to November 30, 1993 (58 FR 54289). This deviation addressed the same concerns that the City and boaters raised in comments on earlier

deviations, which included minimizing land-based traffic impacts from bridge openings, the timing and number of transits, and flotilla requirements. The City had urged more use of weekend openings due to the greater impacts of weekday daytime openings on vehicular traffic. The temporary deviation established ''windows'' for openings on Saturdays and Sundays from 7:00 a.m. to 2:00 p.m., moved the Tuesday and Thursday evening starting time forward to 6:30 p.m., established a Wednesday opening ''window'' between 10:30 a.m. and 2:30 p.m., and added a similar daylight opening for a Federal holiday on October 11, 1993.

On November 29, 1993, the Coast Guard imposed a fifth temporary deviation schedule pursuant to which all recreational boats were required to traverse the river only on weekends during the months following the Fall, 1993 season (58 FR 62532). The Coast Guard invited public comment concerning each of these temporary deviations, and the submittals that it has received have been duly considered in the formulation of this final rule.

2. The 1994 Proposed Final Rule

Following the 1993 boating season, the Coast Guard determined that it had obtained sufficient information to promulgate a new permanent rule. Therefore, on December 22, 1993, the Coast Guard published a notice of proposed rulemaking and notice of public hearing entitled ''Drawbridge Operation Regulation: Chicago River, IL'' (58 FR 67745). That notice proposed to implement a new drawbridge rule that would have required bridges to open for noncommercial vessels during the Spring, Summer, and Fall seasons on Saturdays and Sundays during the day, and on Tuesday and Thursday evenings. During the Winter, the bridges would be required to open on demand, provided that 12-hour advance notice had been given. This schedule reflected elements of the City's request for an approach that would include 24-hour notice, flotillas of 5 to 25 boats, Saturday and Sunday openings from 7:00 a.m. to 7:00 p.m., and Tuesday and Thursday openings from 6:30 p.m. to midnight. The NPRM stated that the Coast Guard had preliminarily determined these days and times were in the best interest of boaters, would provide for safety, and would meet the traffic needs of the City. The Coast Guard invited public comments to be filed, scheduled a hearing on the matter, and received 132 submissions commenting on the proposal. The hearing held on January 20, 1994 in Chicago was attended by 107 persons, of whom 32 made oral statements or furnished data on the proposed regulations. Comments received ranged from those urging that no weekday openings of Chicago draws should be allowed even at night, to those urging the 1976 Rule, which allowed on-demand openings, should remain in place.

Following this notice and comment rulemaking, on April 18, 1994, the Coast Guard promulgated a new final rule for drawbridge operations on the Chicago River (59 FR 18298). As proposed, this rule provided for evening openings on Tuesdays and Thursdays, and openings during the day on Saturdays and Sundays. The rule also provided for Wednesday daylight openings from April 15 through June 15, and specified a flotilla size of between 5 and 25 vessels as a condition for weekday boat runs. In promulgating the rule, the Coast Guard relied on the views expressed during the comment period and at the January 20, 1994 hearing, and on a traffic study submitted by the City of Chicago.

The 1994 rule was challenged in court by Crowley's Yacht Yard, Inc., one of the boatyards located along the Chicago River. On September 26, 1994, the United States District Court for the District of Columbia issued a decision in the case of *Crowley's Yacht Yard, Inc.* v. *Peña* (C.A. No. 94–1152 SSH), rescinding the new rule published on April 18, 1994, and reinstating the previous regulations, that is, the 1976 Rule. The Court's decision, which is published at 863 F. Supp. 18 (D.D.C. 1994), concluded that there was not a sufficient basis in the administrative record to support the Coast Guard's decision to allow weekday daylight openings only in the Spring, and that the data set forth in the traffic study provided by the City were suspect since the study took place, in part, during the ''Taste of Chicago'' festival, which resulted in increased vehicular traffic.

3. The Fall, 1994 Temporary Deviation

Following the Court's decision, the Coast Guard authorized a new temporary deviation to the 1976 Rule for the period October 11, 1994 through December 5, 1994. This temporary deviation was prompted by urgent concerns expressed by the City of Chicago regarding the effect of the reinstated 1976 Rule and was necessitated by the beginning of the ''Fall Return'' when boaters took their vessels from Lake Michigan to the Chicago River boatyards for winter storage. A notice of this temporary deviation, together with a request for comments, was published on October 24, 1994 (59 FR 53351). The deviation provided for openings of bridges on 24-hour advance notice from 7 a.m. to 7 p.m. on Saturdays and Sundays, and on Wednesdays between the hours of 6:30 p.m. and 10 p.m., throughout the remaining Fall season. In addition, from October 11 through October 23 the temporary deviation required that, upon 24-hour advance notice, the bridges were to be opened between the hours of 10:30 a.m. to 1:30 p.m. on Tuesdays and Thursdays, and from October 23 through December 5 the bridges were to be opened for vessel passage between the hours of 10:30 a.m. and 1:30 p.m. on Wednesdays. A 5 to 25 boat flotilla requirement was also imposed as a condition for weekday passages, with only the upper limitations on flotilla size applied to weekend runs. Crowley's Yacht Yard, Inc. challenged the Fall, 1994 temporary deviation before the same court that had stricken the 1994 rule, but the Court denied Crowley's motion to strike the temporary deviation, thereby allowing it to remain in effect throughout the remainder of the Fall, 1994 season.

Following the issuance of the Fall, 1994 deviation, the Coast Guard formally requested the City of Chicago to prepare a new traffic study, and to provide other information that could be used in arriving at a new final rule. The City responded by citing the difficulties of beginning a new traffic study that late into the Fall, 1994 boating season. Instead, it suggested that a study should be conducted during the Spring, 1995 season.

The Coast Guard received 21 comments concerning the deviation that was in effect during the Fall, 1994 season. Data supplied by the City of Chicago indicate that, of the 540 sailboats that returned to winter storage during the Fall, 1994 deviation, 455 traversed the Chicago River on weekends. Specifically, 245 sailboats returned in 16 runs on Saturdays, and 210 transited in 13 runs on Sundays. By contrast, 85 sailboats returned on weekdays and weeknights in a total of 11 runs. Based on these data, the City urged that no future weekday daylight bridge openings were required and that all boaters' needs could be accommodated with weekend openings. However, the City stated that if a temporary deviation was to be implemented for the Spring, 1995 season when Chicago proposed to conduct its traffic study, at the most, bridges should only be required to open on weekends during the day, Wednesday during the day, and Tuesday and Thursday evenings. Chicago also urged that flotilla size

limits and advanced scheduling should be required.

The remainder of the other comments received by the Coast Guard following the issuance of the Fall, 1994 temporary deviation were from boaters or boating interests, and these comments took the position that the Coast Guard should establish a schedule that was more flexible to boaters. These comments generally urged the Coast Guard to implement a temporary rule that allowed a continuation of on-demand openings. Specific comments stated that allowing large flotillas presents inherent dangers to boaters, that some weekday openings are required by boaters, and that special circumstances may require boats to traverse the river at other than scheduled times, such as for repair or in emergencies.

4. The 1995 Temporary Deviation

Given the schedule for the City of Chicago to prepare its traffic study, it was not possible for the Coast Guard to implement a new final rule in time for the Spring, 1995 season. Therefore, it was necessary for another temporary deviation to be implemented for that season. Based on the comments received on the Fall, 1994 deviation, on February 16, 1995, the Coast Guard published a Notice proposing to adopt a new temporary schedule for the Spring, 1995 season that, if finalized, would have allowed on-demand openings of bridges, except during rush hour, and subject to a 24-hour notice requirement (60 Fed. Reg. at 8942). Other than the notice requirement, this proposal would have been similar to the provisions in the 1976 Rule. The Notice ''encourage[d] interested persons to submit written data or views concerning the operation of drawbridges during this deviation period'' and also scheduled a public hearing on the issue for March 9, 1975 (*Id.* at 8941). The Coast Guard stated in its Notice that:

> [T]he hearing will provide all concerned parties with the opportunity to present oral and written statements, with supporting data, to the Coast Guard, for evaluation to determine if any revisions are to be made to the deviation prior to its becoming effective on April 15, 1995.

Id.

The Coast Guard received 80 comments in response to the February 16 Notice. In contrast to the 21 comments received on the prior deviation, the vast majority of the comments received on this Notice took the position that the Coast Guard should not implement a temporary or final drawbridge schedule that allowed a return to on-demand drawbridge openings.

A large number of commenters urged that the Coast Guard should modify its proposed 90-day schedule so that there would be limited, if any, weekday openings of Chicago bridges. By and large, these individuals and Chicago commercial interests stated that the disruptive effect of bridge openings that they had experienced during weekday business hours simply was not in the public interest. Some commenters also stated that the temporary schedule ultimately adopted by the Coast Guard should include requirements for minimum flotilla size to lessen the total number of drawbridge openings.

Aside from general concerns relating to traffic disruption, many commenters stated that their particular business interests were harmed by on-demand openings. These included, among others, taxi cab companies, couriers, parcel delivery services, an ambulance company, hotels, associations, parking companies, property management firms, a bank, DePaul University, Union Station, and AMTRAK.

Accompanying Chicago's submission were letters from both Illinois Senators, 7 Representatives, and 5 alderman calling for a rule that did not allow on-demand bridge openings, particularly on weekdays. Finally, the City urged that while in its view all sailboats could easily be accommodated only with weekend openings, the City was nonetheless amenable to the imposition of a temporary schedule ''of reasonable regulations limiting flotilla size and requiring bridge lifts only on weekends, Tuesday and Thursday evenings and Wednesdays during the day'' for testing purposes.

Representatives from the City of Chicago in their comments to the docket, and in testimony at the public hearing, claimed that all needs of sailboaters could be accommodated by weekend openings. Chicago representatives stated that multiple openings of Chicago's bridges exacerbate problems relating to these aging structures, and pointed out that the total budget for all Chicago bridges is $20 million per year, of which $10 to $20 million goes for rehabilitation of drawbridges. The City claimed that the cost of opening drawbridges averages between $5,000 and $8,000 per boat run, and that the total cost of raising the bridges for the 82 runs under the 1994 deviation was $460,000. Chicago representatives also stated that on-demand bridge openings could not be handled without significant realignment of its bridge tender staff. The City noted that the costs of maintaining and operating the Chicago draws are incurred almost exclusively for the benefit of recreational boaters.

Chicago also produced evidence concerning the potential impact of delays resulting from on-demand bridge openings on emergency fire and rescue efforts. Comments of the City of Chicago Department of Police Traffic Section summarized the potential delays to police, fire and rescue vehicles posed by weekday drawbridge openings, and noted that there is no radio contact with drawbridge tenders.

The Chicago Fire Commissioner, the District Chief of the First District Fire Department, and an employee of the Chicago Department of Environment testified concerning the problems that potentially and actually arise in getting to fire or rescue sites when drawbridges are open, particularly on weekdays. The Deputy Chief of Police for Special Functions and the Commander of the Chicago Police Department and Traffic Section provided similar testimony concerning the effects of bridge openings on law enforcement and other police activities. Others testifying included the Chief of Trauma and Critical Care of Northwestern Memorial Hospital who, citing the need to move serious trauma patients to treatment within fifteen minutes, urged ''as a health care worker * * * stopping all bridges opening in Chicago.''

A representative of the Chicago Development Council, comprised of ''sixty-seven companies which represent over 70 million square feet of commercial real estate space in Chicago's central area'' urged that on-demand drawbridge openings did not properly weigh the needs of Chicago's other citizens. Similar testimony was offered by a representative of the Chicagoland Chamber of Commerce. The Deputy Commissioner for the Department of Planning and Development stated that ''the potential damage to the City of Chicago that would result in the proposed bridge lift [on-demand] regulation far exceeds the benefit to recreational boaters or the recreational boating industry.'' The Director of the Mayor's Office of Special Events offered testimony as to the detrimental effects on tourism of traffic jams caused by bridge openings. All of these statements were consistent with similar statements made by Chicago commercial concerns to the public docket urging that commercial detriment would result from delays relating to on-demand weekday bridge openings.

Boating interests presented their views in 7 comments filed with the Coast Guard. The boating interests urged that no basis had been shown to depart

from the 1976 on-demand rules, that weekday transits were necessary to boaters and to the boatyards that serve them, and that the vehicular and pedestrian disruption noted by the City and other commenters was, in the view of the boating interests, exaggerated. Some of these parties claimed that flotilla requirements were potentially dangerous because a large grouping of sailboats in the Chicago River at any one time heightened the potential for collisions. Some boating commenters also stated that night transits of the Chicago River are inherently dangerous and should not be allowed under the rule.

Boating representatives also appeared at the hearing and continued to voice their need to traverse the Chicago River unencumbered by schedules and, at a minimum, to have the opportunity for daytime weekday transits. Boating interests reiterated their claim that nighttime passages are inherently dangerous, and some charged that flotilla requirements result in large numbers of vessels transiting the river at one time which pose safety risks. The boatyards stated that their client base was shrinking as the result of more restricted bridge openings, and expressed concern that their viability as commercial enterprises was at stake if the Coast Guard moved away from an on-demand approach. Boating interests argued that it was the City's burden to justify any change in the 1976 Rule, and that the City had not provided evidence demonstrating a need for change.

As a result of the public hearing and a reassessment of all the comments received, the Coast Guard promulgated a temporary deviation to the operating schedule of the Chicago River bridges on April 10, 1995 covering the period from April 15, 1995 to July 13, 1995 (60 FR 18006). The temporary schedule departed from the on-demand approach proposed in February, and instead set forth a schedule of daytime and evening openings on Tuesdays and Thursdays as well as weekend openings, maximum sizes for flotillas, and 24-hour advance notice prior to opening, except in emergencies. The temporary deviation attempted to recognize the concerns of the City and business interests by limiting weekday openings. It also addressed and attempted to accommodate the concerns expressed by the boatyards and boaters by not requiring a minimum flotilla size and by providing for transits on four days of the week, including daylight hours on two weekdays. The advance notice requirement was included to allow scheduling of bridge openings by the City, while still being responsive to unanticipated needs for transits by boats.

Crowley's Yacht Yard, Inc. challenged the legality of the Spring, 1995 deviation in court. On May 18, 1995, the United States District Court for the District of Columbia vacated the April 10, 1995 temporary deviation and reinstated the 1976 Rule in effect previously, as promulgated at 33 CFR 117.391 (1993). The Court's decision was premised on its conclusion that the Coast Guard's authority to issue temporary deviations is subject to Administrative Procedure Act constraints, and that, while the Coast Guard had provided notice, comment, and a hearing, the Court did not have before it the administrative record on which the decision was based. The administrative record containing the comments summarized above thereafter was filed with the Court, but the Court refused to reconsider its ruling.

Although the resinstated 1976 Rule provides for opening the bridges ''on signal'' except during rush hours, the drawbridges in fact operated throughout the Spring and Summer of 1995 on scheduled weekend and limited weekday openings through voluntary cooperative agreements between the principal boatyards and the City. This schedule, which was agreed to by the boatyards, was virtually identical to that set forth in the Spring, 1995 temporary deviation that was invalidated by the Court's order upon challenge by Crowley's Yacht Yard, Inc.

Following the March public hearing, the Coast Guard compiled its own summation of boating activity during the Spring of 1995. Coast Guard data show a total of 583 boats transiting between April 15 and July 5, 1995. The City bridge log tallied 498 South Branch and 85 North Branch transit; the Coast Guard observed 488 of those transits. Using the City bridge logs as the baseline number for the boat volume, 73 percent of the South Branch transits occurred during the weekend compared to 79 percent North Branch; 74 percent of the total vessel traffic occurred during the weekend. The Spring outbound monthly breakdown shows April 1995 with 59 transits (10%) over a 15-day period; May 1995 with 371 transits (64%) over a 30-day period; June 1995 with 141 transits (21%) over a 30-day period; and July 1995 with 12 transits (2%) over five days. A total of 52 flotillas was recorded.

5. Negotiated Rulemaking

Simultaneously with the publication of the Spring, 1995 temporary deviation, the Coast Guard published on April 10, 1995 a Notice of Intent to form a negotiated rulemaking committee to bring together representatives of all affected parties to attempt to reach consensus on a new permanent rule (60 FR 18061). Negotiated rulemaking committees provide greater opportunity for meaningful public participation in government decisionmaking.

As detailed above, there have been a wide variety of temporary deviations and a permanent rule addressing bridge operating schedules on the Chicago River. There have also been periods when boatyard owners and City representatives, under the aegis of the Coast Guard, have worked together to schedule openings notwithstanding the availability of an on-demand or other lenient regulatory schedule for openings. The Coast Guard believed that this evidence of cooperation by all interested parties could provide a chance for successful rulemaking through a formal negotiated rulemaking process. Using an experienced and impartial facilitator, the Coast Guard contacted representatives of the City, commercial interests, boatyards, and boaters. They agreed to negotiate in good faith. The Coast Guard chartered a negotiated rulemaking committee in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 561 *et seq.*) (FACA).

The negotiating committee, consisting of representatives of the City of Chicago, Chicago commercial interests, boatyards on the Chicago River system (including Crowley's), the Chicago Yachting Association, and the Coast Guard, met repeatedly to share views and attempted to come to consensus on the best possible operating parameters for the operation of the City of Chicago bridges. Meetings of the committee were open to the public, with opportunities for public input afforded at the end of the committee's formal discussion.

The Organizational Protocols under which the committee met provided that the committee would operate by consensus, meaning there must be no dissent by any member in order for the committee to be viewed as having achieved its goal. The committee's goal was to develop a written statement outlining a permanent schedule for Chicago bridge openings, including proposed rule language ready for publication in the Federal Register. If the committee reached a final consensus on all issues, including the proposed rule language, the Coast Guard could use the consensus language in its notice of proposed rulemaking, and committee members would refrain from commenting negatively on the consensus-based language. If the committee did not reach consensus on

some or all issues, the Coast Guard would draft a notice of proposed rulemaking consistent with any agreed-upon issues, and committee members would retain their right to comment positively or negatively on those aspects of such a notice of proposed rulemaking that were not based on final consensus.

The committee met under the guidance of an experienced neutral facilitator on June 5, 14, 20, 28 and July 12, 1995. Detailed summaries of committee meetings were provided by the facilitator and, after review and approval by the committee, were made available to the public and included in the public docket. During the five, day-long sessions, the committee engaged in detailed discussions concerning the history of drawbridge operations, future concerns, and the goals sought by the interest groups represented.

During the first meeting of the committee, there was an indication that there might be consensus for Saturday and Sunday daytime openings and weekday evening openings, and that only weekday daytime scheduling would be controversial. In the absence of any offers from the other members of the committee to draft regulatory language that would serve as a basis for discussion, the Coast Guard offered to provide a draft schedule for the committee to use at the next meeting.

The second committee meeting was held on June 14, 1995. At that meeting, a representative of Civiltech Engineering, Inc., presented information from the ''Downtown Bascule Bridge Traffic Delay Study'' which that firm had prepared for the City. The City agreed to distribute copies of the backup data volume of the study and to have the Civiltech representative attend the next meeting to answer any further questions. The Coast Guard presented a revised draft of regulatory language for discussion and suggested that the committee should focus on provisions covering recreational vessels. The committee discussed the factors to be addressed in the regulations, including notice requirements, if any, for bridge openings; seasons of the year (i.e., Spring Breakout, Fall Return); direction of passage; days of the week; and hours of the day. While there was some tentative agreement on a number of these items, the central issue of whether and how often drawbridges would be required to open during the daytime on weekdays remained very much unresolved.

The third committee meeting was held on June 20, 1995. There was further discussion at that time of the Civiltech study before the committee turned to the Coast Guard's revised draft of the regulatory language which reflected the tentative areas of agreement from the previous meeting. The committee discussed weekend passage issues including: 20-hour advance notice; no trips out to Lake Michigan starting after noon; no trips in from the lake after 1:00 p.m.; and two bridge lifts per weekend day. After much discussion of weekday daytime openings, however, no member could suggest an approach to this topic that might be mutually acceptable.

The Coast Guard suggested that as of that date, without further study of recently submitted data, and in the absence of consensus, it was inclined to issue a proposed rule covering the Spring and Fall seasons with basic components that included two openings on Saturdays and Sundays, at least one weekday daytime opening, and at least two weekday evening openings.

Most of the committee members found that those terms either provided too few or too many openings. The City stated it strongly preferred no daytime weekdays openings and fewer weekday evening openings. The Chicago Yachting Association stated that Tuesday and Thursday daytime openings are necessary to accommodate the reasonable needs of boaters.

At the fourth meeting held on June 28, 1995, the committee discussed the revised draft language prepared by the Coast Guard and gave contrasting grounds for opposing it, again, with some members arguing that it was too strict and others arguing that it was too lenient. For discussion purposes, the facilitator proposed a schedule framework with the following components: one daytime lift on Wednesday, evening lifts on Mondays and Fridays, two lifts each on Saturdays and Sundays, a minimum flotilla size of 5 boats, opportunities for additional openings for flotillas of 5 or more boats, and an overall cap on the number of boat runs per season. Boaters or their representatives would be required to provide the City with 20-hour advance notice for all of the openings, except for the evening openings which would require 6-hour notice. In addition, the Coast Guard indicated specific operational parameters that might be associated with any schedule of openings that might be developed. The City and Chamber of Commerce agreed to study the facilitator's proposal and the Coast Guard's operational issues. The boatyards and the Yachting Association, however, indicated that their framework would require at least two specified weekday openings. The boating interests also pressed for openings on Tuesday, Wednesday, and Thursday evenings in addition to the Monday and Friday evening boat runs that had been proposed to accommodate transits from and to the lake so that non-emergency repairs could be accomplished without affecting weekend sailing. The boating interests further indicated that they strongly preferred that no maximum number of trips per season be included in the framework. The meeting concluded with the respective frameworks of the Chicago Yachting Association and the facilitator still on the table, but without consensus. The Coast Guard agreed to prepare new drafts of the regulatory language using the facilitator's framework for a starting point.

The last meeting was held on July 12, 1995. The committee discussion started with the two alternative schedule frameworks presented during the previous meeting. The Coast Guard reminded the committee members that its statutory obligation was to ensure the safe passage of vessel traffic while, to the extent practicable and feasible, reducing motor vehicle delays and congestion. The Coast Guard representative further pointed out that it was not the role of the agency to promote one set of economic interests over others and, to that end, any subsequent regulations must be grounded on the best available data on the issues of traffic access, delays, and congestion. The members could not find common ground in either of the two alternatives. A number of variations were discussed, but ultimately consensus simply could not be found on any suggested approach. The negotiated rulemaking concluded with the Coast Guard restating its determination to publish a proposed rule on schedule, which would be finalized in the Fall of 1995.

Despite the fact that the committee did not reach consensus, the Coast Guard nevertheless gained valuable information and insight concerning the issues in this rulemaking from the negotiated rulemaking process.

Discussion of Traffic Study and Recommendations

A. Overview

In the Spring of 1995, the Coast Guard had requested that the City of Chicago prepare a new traffic study to determine the effects of bridge openings on traffic in Chicago's Central Business District. The City of Chicago retained a traffic engineering firm, Civiltech Engineering, Inc., to perform 15-minute directional traffic counts at eleven bridges on fourteen days, and to document their findings in a comprehensive report. The

resulting analysis, entitled City of Chicago Downtown Bascule Bridge Traffic Delay Study, was completed on June 9, 1995 and transmitted to the U.S. Coast Guard Ninth District.

The study was presented and discussed during the negotiated rulemaking process summarized above. In response to questions raised during a review of this document by the City of Chicago, the U.S. Coast Guard, and other parties participating in the negotiated rulemaking, the traffic consultants prepared an addendum to the original study. This addendum was completed on July 20, 1995. Following a review by the City of Chicago, the addendum was transmitted to the U.S. Coast Guard Ninth District, but was not received in time for its findings to be reflected in the Federal Register Notice of August 2, 1995 that announced the proposed regulations. The addendum to the traffic study was entered into the public docket along with the traffic study report of June 9. While the addendum provided greater detail on calculations of delay time, placement of traffic counters (including those on Lakeshore Drive), documentation of delays to emergency vehicles, and other areas addressed in the June 9 report, the addendum did not present findings that were either significant additions to, or contradictory to, the basic findings set forth in the June 9 report.

The traffic study findings presented in this section were summarized from information contained in both the June 9 report and the addendum to that report. The traffic study analyzed more than 35 traffic counts during the Fall of 1994 and Spring of 1995, and avoided collecting any data during holiday and special event periods that may have skewed the data. The Spring, 1995 survey monitored 31 of the 35 boat runs that were scheduled (2 weekend runs and 2 weekday evening runs were not monitored). Of the total number of boat runs that took place during the study period, 22 runs occurred on weekends, 11 runs occurred on weekdays during daytime hours, and only 2 took place on weekday evenings.

To identify average durations of bridge opening and closing cycles during the 1995 Spring Breakout period, nearly 600 individual bridge openings were monitored. The study also attempted to quantify the effect of bridge openings on emergency vehicles by documenting their presence in traffic queues during boat runs. In addition, pedestrian counts were taken on four days at the eleven bridge locations to augment the vehicle traffic data.

The traffic study found that the majority of bridges in downtown Chicago are not exposed to traffic surges normally associated with commuter traffic and instead have traffic volumes that peak sharply on weekday mornings, then decline by an average of only 15 percent and remain at elevated levels into the early evening. By contrast, bridges on major commuter routes such as Lakeshore Drive carried larger volumes of vehicles and experienced traffic surges which peaked sharply in the morning and afternoon rush hours and returned to more moderate flows during off-peak hours. The traffic data collected for this study are consistent with data collected through other planning activities such as the Chicago Area Transportation Study.

Vehicular traffic counts were obtained by using mechanical ''road tube'' counters with electronic timers and by conducting on-site manual counts. Vehicular traffic counts were taken manually when mechanical counting stations could not be placed in close proximity to bridges, or when existing stations could not record traffic that might enter or exit the roadway prior to reaching the bridge or the counting station. Manual counting stations were established at Lakeshore Drive, the Ohio/Ontario Feeder Ramp, and Congress Parkway to record the substantial traffic volumes that actually passed over these bridges.

The Lakeshore Drive bridge, which carries the most vehicles of any structure in this study, had mechanical traffic counters installed at the bridge approaches to confirm the historical traffic counts recorded for this major commuter route. Data from mechanical counting stations for the Lakeshore Drive bridge were consistent with those previously recorded by the Illinois DOT for weekday, weekend, and weekly traffic conditions. The study consultant also performed aerial video surveillance of traffic on several dates during the study period to augment the observations of on-site ground crews monitoring vehicle and pedestrian traffic.

At the time of the Coast Guard's proposed rule, traffic counts for Lakeshore Drive were tentatively discounted by 50 percent while the Coast Guard awaited additional submissions from Chicago concerning whether the reported counts were artificially high due to placement of the mechanical traffic counters in a manner that would have recorded vehicles that did not in fact pass over the bridge. The detailed description of the data collection procedures that was documented in the traffic study addendum revealed that traffic counts were taken by observers actually stationed at the Lakeshore Drive bridge, and supplemented with data from mechanical ''road tube'' counters, thereby confirming the original counts in the traffic study report of June 9.

Pedestrian traffic counts were conducted at the eleven study bridges between 10 a.m. and 4 p.m. on ''typical'' (i.e., no special events) Mondays, Wednesdays, Fridays, and Saturdays. An average of 3,050 pedestrians were counted crossing the eleven study bridges during a typical, non-rush hour, 15-minute period on weekdays. By comparison, only 690 pedestrians were counted crossing these bridges during an average typical weekend 15-minute period. By multiplying these pedestrian counts by the average delays associated with the bridge openings discussed below, it was possible to determine the percentage of total delay experienced by pedestrians as opposed to delays for vehicle occupants.

B. Estimates of Delay

To calculate total person-hours of delay associated with bridge openings, the traffic study measured delays to vehicle occupants and pedestrians at 11 of the downtown bridges during 5 weekday and 3 weekend boat runs. The analysis of traffic delay utilized a computer program (TRAF–NETSIM) developed by the Federal Highway Administration that is a nationally and internationally accepted model for traffic simulation and evaluation. The study did not attempt to calculate the delays incurred by vehicles or pedestrians that took alternative routes to avoid waiting for bridges to close, or the delays which these diversions created for other traffic. Thus, the total city-wide delays associated with bridge openings are likely to be somewhat greater than those reported in the study.

The traffic study monitored bridge openings to determine the effect of flotilla size on the duration of bridge openings and traffic delays. The act of opening a bridge involves sounding a warning, lowering safety gates, and clearing the bridge deck before the leaf(s) can be raised. Once boats have cleared the bridge, the leaf(s) must be lowered and locked and the gates raised before ground-based traffic can resume. In assessing the effect of flotilla size on average bridge ''gate down'' time, the study found that passage of a single boat produced 6.7 minutes of gate down time, while accommodating flotillas of up to 5 boats took one minute longer. Flotillas of up to 10 boats and more than 10 boats had respective gate down times of 8.2 and 9.4 minutes. The study concluded that the majority of time required to open a bridge is attributable

to mechanical and safety constraints rather than flotilla size, and that if minimizing delays is an objective of bridge lift operations, minimum flotilla sizes should be considered when regulating these openings.

Data analysis for the 11 bridge sites showed that average weekday boat runs resulted in a total of 2,024 person-hours of delay, while weekend boat runs caused an average of 1,034 person-hours of delay. Data from the 11 study sites were extrapolated to estimate boat run delays at all of the 25 downtown bridge based on historic vehicle and pedestrian traffic data provided by the Chicago Department of Transportation (DOT) and the Illinois DOT. Based upon these extrapolations, it was estimated that average weekday boat runs would generate 2,724 person-hours of delay and weekend runs would produce 1,260 person-hours of delay. In summary, the person-hours of delay attributable to weekend bridge openings were found to be less than half of those caused by weekday openings.

The consultant also expressed findings of traffic delay in terms of the average number of persons and vehicles affected by bridge openings that accommodated the passage of an average-sized flotilla. On-site monitoring of the Spring, 1995 Breakout boat runs found that an average weekday flotilla included 7 boats and that bridges took an average of 8 minutes to open and close and 4 minutes for ground-based traffic to recover (12 total minutes of delay). Using the number of vehicles, vehicle occupants, and pedestrians as metrics, the consultant estimated that a weekday boat run of 7 boats caused a 12-minute delay for an average of 13,620 people and 5,360 vehicles. A similar quantification of impacts for people and vehicles was calculated based on weekend boat runs that averaged 12 boats per flotilla. An average weekend boat run of 12 vessels produced 12-minute delays for 6,300 people and 3,540 vehicles.

C. Impacts on Emergency Services

At the request of the City of Chicago, the traffic study also documented instances where emergency vehicles were delayed by bridge openings. The City has historically voiced its concern that bridge openings compromise police, fire department, and ambulance services by impeding their response to emergency calls and by delaying their return to their bases of operation. Delays by emergency response vehicles were documented in the traffic study by the notes of on-site traffic monitors, in Mobile Intensive Care Unit Report logs maintained by the Chicago Fire Department, and in the Bridge Lift Logs of the Chicago DOT. The traffic study found that 83 percent of the weekday boat runs were associated with the delay of at least one emergency vehicle, and similar delays were recorded for 26 percent of the weekend runs.

D. Study Findings Relevant to Final Rule

The traffic analysis for downtown Chicago found consistent patterns of normal vehicle and pedestrian movement (i.e., no special events) that were directly attributable to factors of time of day and days of the week. Outlined below are the major factors that were considered in formulating the final rule. The following conclusions of the study are shown with a list of the relevant study findings.

(a) If traffic impacts and their consequent delays are to be minimized, maximum opportunity should be afforded to schedule boat runs on weekends and evenings rather than during weekday daylight hours.

(1) Pedestrian and vehicle traffic volumes on weekdays were approximately double those recorded on weekends.

(2) Weekday evening traffic volumes on most downtown streets fall to levels that are at or below those which are experienced on weekend mornings.

(b) If boat runs are to be made on weekdays, the runs should be scheduled during times when bridge lifts would generate the least amount of vehicular and pedestrian traffic delay.

(1) Weekday vehicle traffic volumes on commuter routes (e.g., Lakeshore Drive) peak sharply during morning and evening rush hours (i.e., 7:00–10:00 a.m. and 4:00–7:00 p.m) and return to more moderate volumes during off-peak hours.

(2) Other streets in the study sample had weekday traffic volumes that remained fairly consistent throughout the day, declining only slightly from morning/evening peak periods.

(3) Pedestrians experienced 22 percent of the total person-hours of delay associated with weekday daytime boat runs and 11 percent of the total person-hours of delay created by weekend boat runs.

(c) If a future schedule for boat runs is to reflect recent patterns of boaters' requests for transit, at least some opportunity should be afforded for periodic weekday daytime and evening runs.

(1) For boat runs monitored during the study period, 92 of 359 boats (25 percent) made runs on weekdays/evenings.

(d) If provisions for weekday daylight boat runs are to be sensitive to the impacts of bridge lifts on traffic delays, requirements for minimum flotilla size should be considered.

(1) The time needed to carry out the mechanical process and safety precautions during bridge lifts exceeds that which is usually required for the transit of boats in Chicago.

(2) Bridge lifts to accommodate flotillas of up to 5 boats produced delays only 15 percent greater than those generated by single-boat passages.

(3) Of the eleven weekday daylight runs that were monitored during the study, two runs accommodated only one boat and two others accommodated two and three boats, respectively.

(e) Bridge lifts to accommodate boat runs do impact emergency vehicles, with far greater impacts associated with weekday daytime boat runs than with weekend runs.

(1) At least one emergency vehicle was impacted during 83 percent of the weekday boat runs monitored in the study; only 26 percent of the weekend boat runs delayed at least one emergency vehicle.

The 1995 Final Rule

When the participants in the negotiated rulemaking proceeding were unable to reach consensus, the Coast Guard published a new Notice of Proposed Rulemaking (NPRM) on August 2, 1995 (60 FR 39287). The Notice proposed to adopt a new Final Rule that would set the following schedule for the opening of Chicago drawbridges during the boating season:

(1) On Saturdays and Sundays openings to accommodate two transits would be available each day, if requested 20 hours in advance of the intended time of passage, without regard to the number of vessels.

(2) Weekday daytime openings, with no minimum flotilla requirement, would be limited to Wednesday morning after 10 a.m., with 20-hour advance notice.

(3) On Monday and Friday evenings, after 6:30 p.m., the bridges would be required to open to accommodate transits, if requested 6 hours in advance, with no minimum flotilla requirement.

(4) In addition to the above openings, which would be available for the passage of one or more vessels, supplemental openings could be scheduled for flotillas of 5 or more vessels, with 20-hour advance notice. These openings could not be requested for rush hour periods.

After reviewing the comments received, the Coast Guard's final rule adopts this schedule, which the Coast

Guard has concluded best serves the public interest. As explained in the NPRM, the Coast Guard thought that the rule reasonably accommodated the needs of boaters and vehicular and pedestrian traffic. As the following analysis shows, the comments received on the NPRM do not alter the basis for this determination. However, the NPRM itself was based upon an extensive array of information compiled over the last two years, and reflected the Coast Guard's confidence that this bridge opening schedule represents the best possible balance of all interests that can be achieved. The final rule also continues the past practice of allowing vessels to transit the river in emergencies under special arrangements and without flotilla requirements.

Two openings on each of the weekend days with no flotilla requirements were selected to accommodate what is generally agreed and shown by the administrative record to be the busiest and most appropriate time period for the heavy Spring Breakout and Fall Return recreational traffic. The Coast Guard found significant concurrence with this approach during the negotiated rulemaking, although no consensus was reached. These openings are on days that have been most-utilized by boaters and also are days when daytime vehicular traffic is at its lowest volume.

Monday and Friday weekday evening openings with significantly shorter (6 hour) advance notice were provided to meet any possible late supplements to demands for breakout and return passages, and to meet the need of a single boater to have access for non-emergency repairs at the beginning of a week in order to return to the lake for the next weekend's recreation. Although concerns have been raised by boaters about the safety of evening passages, a passage beginning shortly after 6:30 p.m. would be conducted in daylight during the extended daylight hours that coincide with most of the boating season. Moreover, these evening hours are intended as a supplement to the weekend and Wednesday daytime openings provided by the rule. Past data and experience indicate that fewer boaters may actually use this option, but it is there for those who need it. As noted above, the possibility of Monday and Friday evening openings was discussed at length by all parties in the course of the negotiated rulemaking proceeding. While no consensus was reached on this issue, the Coast Guard believes that openings on these evenings provide some of the additional flexibility sought by boating interests, and can help to accommodate scheduling of mid-week repairs at the boatyards. The scheduled times of these openings should also minimize negative impacts on vehicular traffic.

It should be noted that, in addition to considering the needs of boaters to make normal repairs during the boating season, the Coast Guard recognizes that situations may arise where a true emergency repair involving the substantial value of a boat may occur that cannot be accommodated by scheduled openings. The Coast Guard's rule explicitly provides that the general requirement, Subpart A, in 33 CFR Part 117, direct the opening of bridges for vessels in distress where a delay would endanger life or property.

A Wednesday post-morning rush hour opening without flotilla requirements was selected based on information in the administrative record supporting Wednesday as a weekday chosen historically by boaters for transit, and to minimize the time between potential single vessel passages. The Coast Guard believes that providing a scheduled weekday opening with 20-hour advance notice will provide the necessary predictability and notification time to minimize the impact on congestion and avoid unacceptable delays to emergency vehicles. The Coast Guard recognizes that weekday daytime drawbridge openings are disruptive to vehicular traffic, but this fact must be weighed against the constraints of providing only evening passages to boaters. Ultimately, the Coast Guard believes that a Wednesday daytime openings, in addition to weekend openings, is a reasonable compromise. The need to accommodate mid-week daytime transits for non-emergency repairs was addressed by both the boaters and the boatyards. The boatyards claimed that they had experienced a decline in their summer repair business, although no documentation was submitted to confirm their losses. The need for both daytime and evening weekday openings also received the attention of the participants during the negotiated rulemaking proceeding. The Coast Guard believes that a balanced schedule of predictable bridge openings is in the public interest and will benefit all parties from the standpoint of planning future activities.

The regulations allow additional non-rush hour openings to be scheduled for flotillas of five or more vessels with 20-hour advance notice. This provision responds to the assertion of the boating interests that flexibility in the schedule can reduce the overall number of openings. Based on previous usage of the Chicago River by sailboaters, it is anticipated that this provision will be used primarily to schedule additional breakout and return passages, but it could also be used to bundle trips for non-emergency repair work. Although the City asserts that any allowance for openings for supplemental flotillas will compromise the other scheduled openings' reductions of traffic delays and congestion, the Coast Guard expects that the advance scheduling of these openings and their announcement in the media would provide appropriate notice to land-based traffic and emergency services. Moreover, the flotilla requirement will also serve to reduce the frequency of disruptions caused by additional passage opportunities.

Finally, the Coast Guard decided not to adopt two other potential variations to the regulations. Although there have been concerns raised by many boaters about the safety of evening passages, scheduling openings for all or more weekday evenings had been suggested by various boating interests during the negotiated rulemaking. The Coast Guard has concluded that the volume of recreational traffic simply does not require additional scheduled evening openings, especially in light of the provision for supplemental flotilla openings, and in light of the boaters' oft-stated position that they do not prefer to transit the river at night. On a second issue, the City had requested that the Coast Guard implement a procedure to penalize boaters who are ''no-shows'' at pre-arranged openings. The Coast Guard has not been presented with any data indicating that boaters are abusing agreements on openings and therefore such a regulatory response would not be warranted.

The comments received by the Coast Guard and the positions articulated at the August 22, 1995 hearing indicate that a compromise such as the new rule is required, and underscores what has been apparent from the outset of this proceeding. The Chicago boating interests and the City of Chicago, along with its non-boating commercial enterprises, have diametrically opposed and strongly held views concerning when Chicago's bridges should be required to open. Any solution will necessarily be a compromise that will not fully accommodate the needs of any one party.

Approximately 25 businesses, associations, organizations and individuals who were not boaters or otherwise affiliated with sailing claimed that the Coast Guard's proposed rule was too permissive. These commenters stated that bridge openings impeded vehicular and pedestrian traffic in the Chicago downtown area, that weekday openings impermissibly constrained

commerce, and that openings undermine the critical need of Chicago's substantial business and residential communities for uninterrupted access to the Loop. These commenters included individuals, businesses, commercial centers, taxicab companies, a delivery service, real estate concerns, office buildings, the Chicagoland Chamber of Commerce, DePaul University, and community associations. All of these parties opposed the proposed rule and urged that there is no necessity for Chicago bridges to open except on weekends and occasional weekday evenings.

By contrast, the majority of boaters or other parties affiliated with sailing viewed the proposed rule as being too strict, and that there was no need to change the on-demand approach embodied in the 1976 Rule. These commenters urged that daylight openings are required in order to safely transit the Chicago River, that evening openings are inherently dangerous, that large flotillas create the potential for collisions, that boaters should have the right to unfettered passage on the river, and that maintenance problems were the real reason for bridge-related delays. Virtually all of these commenters claimed that on-demand openings every day were required. These parties also urged that unexpected situations required passage on the river without long advance notice and flotilla requirements.

The claim by the boating community that they should have the right to unfettered passage on the river is at odds with the 1988 statutory change in 33 U.S.C. 499 that specifically requires the Coast Guard to balance land and water transportation needs. The comment that maintenance problems were a major cause of bridge-related delays is also inconsistent with findings of the traffic study commissioned by the City of Chicago. In fact, the traffic study found that 1995 bridge opening cycle times were 20 percent faster than 1994 cycle times—a condition which the traffic study attributed to fewer malfunctions, better maintenance, more efficient bridge crews, and more efficient boat operations.

During the course of the August 22, 1995 hearing, testimony was heard from eight parties. On behalf of the City, Mr. Roger Kiley, Chief of Staff to the Mayor, opposed the proposed rule, urging that bridge openings should be allowed only on weekends and on weekday evenings, with minimum and maximum flotilla sizes. Mr. Kiley stated that over the years the number of sailboats requesting bridge openings remained a relatively constant 550 to 650 boats. Mr. Kiley urged that the issue is whether ''these few recreational boats need unimpeded access to the river in light of the overwhelming data submitted by the City and the lack of any contrary data provided by the boatyards.'' Mr. Kiley argued on behalf of Chicago that the Coast Guard's proposed rules do not properly balance the needs of ''more than 5,000 vehicles affected each time bridges open during the weekday'' and the ''thousands of pedestrians and public transit users who are similarly inconvenienced.'' Mr. Kiley stated that traffic backups occasioned by bridge openings can extend a half-mile or more, and that it can take up to ten or more minutes following closure of a bridge for traffic to return to normal. The City argued that the Coast Guard's proposed rule would accord too much flexibility to boaters and ''fails to strike the necessary balance between boating and land-based transportation interests.''

Dr. Marcel Martin, Chief of Trauma and Critical Care at Northwestern Memorial Hospital, testified that delays in transporting patients to emergency rooms negatively affect the ability of medical staff to resuscitate patients. In Dr. Martin's words, ''a few minutes may make a difference between life and death.'' Dr. Martin questioned the usefulness of the provisions in the proposed rule allowing drawbridges to close for emergency vehicles in light of these time constraints, and similarly questioned the Coast Guard's conclusion that other routes could be utilized by emergency vehicles. In Dr. Martin's view this raised the possibility of an unacceptable ''compromise in time.''

Mr. Grant Crowley testified on behalf of Crowley's Yacht Yard, Inc. Mr. Crowley stated that the re-examination of the Chicago drawbridge rules was originally occasioned by Chicago's desire to build a new transit system, the Circulator. Mr. Crowley also questioned the viability of traffic data submitted by the City, including that for Lakeshore Drive, and took the position that the boatyards should not be required to produce economic data that supported the continuation of the 1976 Rule. He argued that traffic is not inordinately delayed by bridge openings and that the rulemaking process is, in his opinion, arbitrary and capricious. Mr. Crowley further stated that, in his view, traffic returns to normal in four minutes following the closure of bridges. He additionally urged that requiring bridges to open 150 times per year is not unreasonable since other Chicago bridges open much more frequently than this.

Mr. Vic Peterson of AAA Boatyard stated that this company had lost income from summer boat repairs as a result of restricted openings of Chicago drawbridges. He urged that reasonable passage had to be assured by any new rule.

Mr. Bernard Ford spoke on behalf of the Chicagoland Chamber of Commerce, which he characterized as the largest business organization in Chicago. Mr. Ford discounted any effect of the proposed Circulator transit system on the pending rulemaking. He stated that the Chamber of Commerce did not favor the proposed rule and originally wanted a rule that would have been even more restrictive than that proposed by Chicago. Mr. Ford said that the Chamber of Commerce's review of the data submitted by the City indicate that ''no weekday daytime bridge openings are needed.

Finally, three boat owners testified. They variously claimed that bridge problems were directly related to maintenance problems, that night travel is ''definitely more hazardous than daytime travel,'' that allowing large flotillas keeps the bridges up longer and such flotillas are potentially hazardous to boaters, that individual boaters need the opportunity to transit alone for repairs or in emergencies, that boat owners, unlike vehicles, have no alternative routes for transit, and that bridge openings are not realistically a problem for downtown businesses.

Analysis of the Final Rule

The long and detailed preamble to this final rule is due to the complex nature of the issues involved, the lengthy public process that preceded that final rule document, and the prior litigation on this subject. Supporters of the two main interest groups have tended to present maximalist positions: boating interests have claimed that no changes to a well-functioning regulation are needed, and the land-based interests have claimed that a schedule that limits openings to weekends and perhaps weekday evenings is all that is necessary. The Coast Guard believes there is a reasonable, practical, and feasible middle ground, and has concluded that there is ample reason to implement its final rule.

As stated in the notice announcing the establishment of the negotiated rulemaking committee, the Coast Guard is committed to proceeding to a final rule for the end of the 1995 boating season when recreational vessels are leaving Lake Michigan for winter storage. In the absence of a consensus-based rule, the Coast Guard's final rule is based on the extensive administrative

record that the Coast Guard has assembled to date, the information obtained from the negotiation process, and its professional judgment. In particular, the Coast Guard's final rule incorporates weekend openings, advance notice requirements, and weekday evening openings that received support by some committee members, although not unanimous consensus in a formal committee report. Weekday openings were clearly the most contentious issue, which the Coast Guard is resolving by scheduling one mid-week opening without flotilla requirements and authorizing unlimited opportunities for additional openings for flotillas of at least five vessels. The Coast Guard's solution does not match the negotiating position of either the City, which bargained for no weekday openings, or the boatyards and boaters which wanted on-demand openings every day of the week. On this issue, the Coast Guard determined that a compromise was necessary to meet the needs of both groups and the public interest. The analysis of the final rule can be best summarized by responding to the comments submitted to the NPRM public docket by the attorney for Crowley's Yacht Yard, Inc. and by the City of Chicago.

Written comments to the August 2, 1995 NPRM public docket submitted by the attorney for Crowley's, one of the boatyards on the Chicago River, discussed five topics. Each of these topics is addressed below in the Coast Guard's detailed response to this submission. However, no changes to the operating schedule proposed in the NPRM were made as a result of these comments because they did not offer any additional material facts for the Coast Guard to consider.

The first comment asserts that no legitimate reason has been identified for altering an existing regulation that has worked well for many years. The City of Chicago requested that the Coast Guard initiate a rulemaking to change a basically on-demand system that provided maximum flexibility and access for waterborne transportation. The City and every non-boating interest that has participated in this two-year proceeding has argued that the current system is not equitable to the surface transportation needs of commercial, emergency, and other traffic in a major metropolitan center. The City's request was made in the context of a legislative change that now requires the Coast Guard, acting on the delegation of the Secretary of Transportation, to the extent practical and feasible, to establish rules that provide a schedule of openings that will help reduce traffic delays and congestion. The Coast Guard's decision to change the regulations is consistent with its statutory mandate and supported by the traffic study submitted by the City and analyzed elsewhere in the preamble.

The statement that the existing regulation is working well is simply incorrect and is belied by the record, which contains ample evidence that on-demand openings are opposed by all non-boating parties in Chicago and have a disruptive effect on Chicago traffic and commerce, as is indicated not only by comments but by the traffic study. Furthermore, the actual operations under the existing regulation are based on agreements by the boatyards and the City to schedule openings. This approach has required significant and continuing involvement by, and costs to, the Coast Guard as shown in letters and other documents in the administrative record: to remind the parties to initiate scheduling, to facilitate compromises, to interpret agreements, to monitor implementation, and to mediate disagreements. The final rule, by contrast, gives notice to the public of the operating procedures and schedule to be followed and allows Coast Guard resources to be properly focused on enforcement.

The second comment asserts that there is no basis for the NPRM and, by extension, the adoption of the proposal as a final rule. The comment is based on a perception of significant flaws in the traffic study requested by the Coast Guard and submitted by the City of Chicago. The Coast Guard's analysis and use of the study findings to support its final determination are explained separately in the preamble. In addition, the comment overlooks significant information that the Coast Guard received from the negotiated rulemaking and other data available to it. As discussed under the section on the negotiated rulemaking, the Coast Guard has based its new regulations on matters addressed in the public record, including areas where support, although not consensus, was reported in the negotiation process. Given the record of this proceeding, there is clearly a basis for an NPRM proposing a reasonable compromise aimed at accommodating the public interest.

The third comment asserts that important Coast Guard reports were ignored in developing the proposed regulations. As mentioned above, the absence of predictable and permanent regulations in this area has required significant Coast Guard resources to be applied to facilitate bridge openings. For the 1995 Spring Breakout, Coast Guard personnel were assigned to observe and report on drawbridge openings for recreational boaters. The purpose of these reports was to ensure that agreements between the boatyards and the City were carried out and that passage of boats was achieved safely. These reports were not intended to record traffic impacts or to supplement professionally-conducted traffic studies, but to the extent that this information has been relevant to traffic and boating operations it has been considered, as discussed above.

In developing the proposed rules, adopted without change as final by this document, the Coast Guard has relied on the following: traffic study findings and data submitted by the City of Chicago, the reports on and experience gained from an unsuccessful negotiated rulemaking, analyses of numerous submissions to this and earlier rulemaking and administrative dockets, and the Coast Guard's professional judgment gained from monitoring and overseeing the operation of the Chicago drawbridge system and other drawbridges throughout the United States. All of this played a part in formulating the new rule.

The fourth comment asserts that certain elements of the rulemaking are arbitrary and capricious. Again, this is simply not so. The Coast Guard's final rule is based on exhaustive consideration of the factors discussed above and on its determination that a predictable schedule that still affords flexibility to the boaters and predictability to the City will stabilize the relationship between the boatyards and the City, meet to a substantial degree the expressed concerns of all groups, and reduce Coast Guard involvement in day-to-day disputes. As is evident from the discussion in this preamble, there is ample support in both the record and the law for the rule that the Coast Guard has adopted.

The fifth comment criticizes the Coast Guard's response to various administrative requirements beyond the Administrative Procedure Act. Despite the expedited schedule for issuing a NPRM, the requisite discussions in response to the Regulatory Flexibility Act and Executive Order 12866 were included in the NPRM. This matter is addressed more fully in the following section of this preamble. The discussion there fully supports the Coast Guard's determination made in this final rule.

Significant comments on the August 2, 1995 NPRM were also received from the City of Chicago. Chicago opposed implementation of the proposed rule, and objected to the rationale outlined by the Coast Guard. Chicago stated that the rule ''provides none of the relief that the

City sought'' and that it ''perpetuates weekday daytime openings to meet the needs of less than 100 boaters'' despite the fact that ''at least 3000 vehicles are delayed each time a bridge is opened.'' The City of Chicago also stated that despite a specific request in the NPRM that the boatyards provide data to show how they are in fact negatively impacted by a rule containing scheduled openings, no such data were ever provided. In the absence of such data, the City of Chicago urged that weekend openings are all that is required.

As discussed previously, the Coast Guard is not unmindful of these concerns. But the Coast Guard has determined for the reasons articulated by the boatyards and boaters that some weekday openings should be allowed. While quantitative data were not supplied by the boatyards, concerns about any overly-restrictive access schedule were voiced by many boaters. The approach adopted in the final rule, which allows weekday openings only on Wednesdays, is a reasonable accommodation between the needs of boaters for the flexibility afforded by some weekday daytime passages and the needs of Chicago and its citizens to limit daylight openings to a schedule that is predictable and that does not unnecessarily result in vehicle delays and congestion on Chicago streets. The specific points raised in Chicago's comments are discussed below.

First, the City states that it should not be required to raise two or more bridges at a time since this places undue burdens on the bridge system and on traffic. As the City notes, however, drawbridge openings are in large respect dependent on flotilla size. Thus, the more opportunity there is for boaters to transit the river, the more reasonably-sized individual flotillas can be. While on-demand openings have the potential for repeated disruption of Chicago traffic, in the Coast Guard's view the rule affords enough reasonable windows of opportunity for boaters to schedule their runs between the boatyards and Lake Michigan so as to encourage reasonably-sized flotillas to be formed. The rule's provision for additional boat runs for flotillas of 5 or more boats provides more opportunities for river passages, gives the City and boatyards the flexibility to accommodate reasonably-sized flotillas as necessary, and accommodates additional vessels at the earliest available time. The Coast Guard believes this approach answers the expressed needs of boaters for flexibility and reduces the potential disruption to Chicago traffic occasioned by large flotillas that might be required if daylight openings were more restricted. This approach also minimizes the problems concerning the opening of the Lake and Wells Street bridges, which the City notes are dependent on Chicago Transit Authority train movements.

Second, the City states that the rule should impose a means to prevent or curtail the possibility that boaters will request a bridge opening and then not show up at the scheduled time. As previously noted, the Coast Guard is not adopting such a provision at this time since no data have been provided to the Coast Guard that would confirm a problem concerning ''no shows.'' As a result, the Coast Guard does not believe that this matter is a significant problem that necessitates regulatory intervention.

Third, the City states that the rule ''ignores the impact on emergency vehicle response times.'' The rule does not ignore this issue, and the potential for emergency vehicles being delayed by bridge openings has in fact received the Coast Guard's careful attention. The Coast Guard has noted, and discussed above, the fact that the traffic study commissioned by the City reports instances of emergency vehicle delays occasioned by bridge openings, and that the possibility of these delays is greatest during weekday daylight openings. Limiting the times at which bridges are opened, of course, limits the times when these delays could occur. The Coast Guard recognizes fully that weekend openings run less of a risk of delaying emergency vehicles since traffic is lighter than on weekdays, and concomitantly that allowing daylight weekday openings—even when limited solely to Wednesdays—runs the risk that emergency vehicles will be delayed as a result. But again, the Coast Guard has concluded that there is a basis and a need for allowing some limited, non-weekend, daylight openings. The Coast Guard believes that its approach of allowing Wednesday daylight openings accommodates reasonably the stated needs of boaters for weekday passages, while minimizing the likelihood of emergency vehicle delays.

Fourth, the City states that the Coast Guard may be wrong in its premise that bridge openings on the North and South Branch bridges do not impact Chicago traffic as much as openings on the Main Branch of the river. The data in the traffic study bear out the Coast Guard's conclusion, and in developing the final rule the Coast Guard has considered these data on the impacts of bridge openings on vehicle traffic crossing the North and South Branch bridges. The Coast Guard's decision to restrict openings to weekends, specific weekday evenings, and one weekday during daylight hours, is designed to practically address the needs of boaters without unduly disrupting the substantial vehicular traffic that passes over the North and South Branch bridges during weekday daylight hours.

The City also addresses several other issues. It takes exception with Coast Guard's statement in the preamble of the NPRM that there is evidence of deterioration in Chicago's bridges and notes that it has made great investments in its bridges. Nonetheless, Chicago's own prior comments, as well as the traffic study the City commissioned, have noted occasions of bridge malfunctions. Chicago also states that the Michigan Avenue bridge accident and freight tunnel flooding in 1992 should not be characterized as the basis for the City's request for new bridge regulations. These events were discussed by the City in prior correspondence, but as is evident from the analysis set forth in this preamble, the rule that the Coast Guard is adopting results from an extensive review of the articulated needs of the public, including boaters, vehicular traffic, individuals, and businesses, not from these past extraordinary events.

Chicago also recommends that, due to reconstruction, the Randolph and Loomis Street bridges should now be placed under the 30-minute notice requirement for commercial bridge openings, and that the Ogden Avenue bridge has been removed and therefore should be deleted from the lists of bridges subject to 30-minute notice requirement by commercial vessels. The Coast Guard agrees and has adopted this last comment.

Reasons for Effective Date

In the notice announcing the formation of the negotiated rulemaking committee, the Coast Guard indicated its intent to have rules in place during the Fall, 1995 recreational boating season. That intent was repeated in the NPRM. Due to the time needed to produce a fully comprehensive and explanatory final rule, this final rule is being published shortly after the beginning of the Fall Return.

As this final rule was being written, representatives of the City of Chicago and boating interests met on September 20, 1995 under the auspices of the Coast Guard and agreed on a schedule for the 1995 Fall Return. This temporary schedule tracks closely to the final rule and includes openings on Saturday and Sunday mornings, Wednesday mornings following rush hour, along with approximately five scheduled supplemental weekday openings. It is the expectation of the Coast Guard,

based on the agreement of the City and the boatyards, that this schedule will bring the 1995 boating season to an amicable and successful conclusion. Therefore, the Coast Guard has made this rule effective on November 19, 1995, following the expiration of the Fall Return schedule agreed upon by the City and the boatyards. It should be emphasized that the flexibility and scheduling aspects of the Coast Guard's rule are consistent with the schedule agreed to by the boatyards and the City. This indicates that future seasonal boat runs should be able to proceed under the rule without untoward problems for the City or the boatyards and without continued diversion of Coast Guard resources.

Regulatory Process

A. Regulatory Evaluation

The Coast Guard has determined that this rule is not a significant rulemaking activity under Executive Order 12886 and the Department of Transportation's Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). The Coast Guard has received extensive information from the City of Chicago on the costs associated with operating drawbridges to accommodate transits of recreational sailboats. Despite repeated requests to the boatyards, these businesses have provided the Coast Guard only with general allegations of lost profits and have not provided the Coast Guard with comparable information on the financial impacts that they would experience as a result of a more limited schedule of drawbridge openings. The final rule is not seen as having a significant adverse economic impact on any other businesses.

No requirements for commercial transits are affected by this rulemaking. As a matter of record, most commercial transits consist of barges which typically do not require bridge openings. In addition, there are virtually no recreational vessel transits during the off-season and the requirements governing recreational transits during the off-season are expected to have little or no economic impact.

The rule does not constitute a ''taking'' under the Fifth Amendment to the Constitution, as discussed in E.O. 12630 and the Attorney General's Guidelines implementing that Order. The Coast Guard has determined that the regulation will substantially advance the governmental purpose of balancing the needs of land-based transpiration and the navigational rights of recreational boaters. The provisions for supplemental openings for flotillas of five or more vessels and the provision ensuring access by all single vessels on five out of the seven days in each week should minimize the economic impact, if any, on the boatyards.

B. Small Entities

The Regulatory Flexibility Act requires an assessment of whether the rule would have a significant economic impact on a substantial number of small entities. The Coast Guard has concluded the rule would not have such an impact and, therefore, a detailed regulatory flexibility analysis has not been undertaken. Nonetheless, the Coast Guard has weighed the potential impact of the rule on small entities.

For this rule, the Coast Guard considers any business employing less than 500 persons to be a small entity. The four boatyards remaining on the North and South Branches of the Chicago River are small businesses, and they have asserted that restricting the drawbridge openings will adversely affect their businesses. However, the Coast Guard also received a number of comments from other small businesses in the area that asserted that on-demand openings adversely affected their operations. The small businesses that objected to the on-demand openings included, among others, taxi companies, delivery services, and small shops in downtown Chicago.

As discussed elsewhere in the preamble, the Coast Guard has carefully considered the views of the boatyards and of other small businesses that might be affected. The rule allows scheduled openings on five days of the week for single vessels in addition to allowing additional openings at all times, other than rush hour periods, for flotillas of five or more vessels. This approach is more flexible to boating interests than any of the prior temporary schedules implemented by the Coast Guard and also provides more opportunities for transit than did the 1994 rule. As noted above, the rule provides for drawbridge openings on days and at times when sailboaters have traditionally traversed the river. Specifically, the schedule provided for in the rule is also consistent with the requirements of boatyards as evidenced by the fact that it would accommodate recreational transits on the dates and at the time times agreed to by the boatyards during those periods in the past two years when drawbridge openings have been set pursuant to negotiations between the City and the boatyards. There is no basis for concluding that the boatyards will be significantly harmed by such an approach. As a result, the Coast Guard has concluded that the rule should have no significant impact on the operations of the boatyards. In addition to allowing on-demand openings for boats needing emergency repairs, the openings prescribed by the rule will allow any vessel that needs non-emergency repairs to transit the river for mid-week service and return to Lake Michigan in time for sailing on the following weekend.

This provision answers expressed concerns by boaters and the boatyards during the comment periods and the negotiated rulemaking process. The schedule of boat runs emphasizes openings on evenings and weekends, and this will minimize the impact of openings on other small businesses in the area. While these entities by and large called for no weekday openings at all, the Coast Guard has determined, as explained above, that some such openings are necessary to meet the navigational needs of boaters. The schedule of openings and advance notice requirements set forth in the rule affords more certainty and predictability to this process and therefore will be more beneficial to small business than a continuation of the 1976 on-demand rule.

Therefore, the Coast Guard certifies under 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) that this regulation will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). No reports or information would be submitted to the government. As in common with other drawbridge regulations, persons desiring passage of a vessel have to make their requests known to the operator of a drawbridge some time in advance. This advance notice is normally a single phone call, even when there is a flotilla of several vessels. Advance notice has been required under the existing rule for drawbridges on the Chicago River, and a simple verbal request for bridge openings would continue to be required under the new rules.

Federalism

The Coast Guard has analyzed this action under the principles and criteria contained in Executive Order 12612 and has determined that this regulation involves only an area within Chicago and, therefore, will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under section 2.B.2.g.5 of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation. A Categorical Exclusion Determination statement has been prepared and placed in the docket.

List of Subjects in 33 CFR Part 117

Bridges.

For reasons set out in the preamble, the Coast Guard amends 33 CFR Part 117 as follows:

PART 117—DRAWBRIDGE OPERATING REGULATIONS

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

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); Section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.391 is revised to read as follows:

§ 117.391 Chicago River.

The draws of the bridges operated by the City of Chicago shall operate as follows:

(a) For commercial vessels:

(1) From April 1 through November 30—

(i) The draws of the bridges across the Chicago River from its mouth to the junction of the North and South Branches, across the South Branch from the junction to and including the Roosevelt Road, and the Kinzie and Ohio Street bridges across the North Branch shall open on signal; except that, from Monday through Friday from 7:30 a.m. to 10 a.m., and 4 p.m. to 6:30 p.m., the draws need not be opened for the passage of commercial vessels.

(ii) The draws of the bridges across the North Branch of the Chicago River at Grand Avenue, the bridges across the North Branch of the Chicago River north of the Ohio Street bridge to and including North Halsted Street, and bridges across the South Branch of the Chicago River North of South Halsted Street to, but not including Roosevelt Road, shall open on signal; except that, from Monday through Friday from 7 a.m. to 8 a.m. and 5:30 p.m. to 6:30 p.m., the draws need not open for the passage of commercial vessels.

(iii) The draws of the bridges across the North Branch of the Chicago River north of North Halsted Street and the South Branch of the Chicago River south of South Halsted Street shall open on signal; except that, from Monday through Friday from 7 a.m. to 8 a.m. and 5:30 p.m. to 6:30 p.m. the draws need not be opened for the passage of commercial vessels.

(iv) Subject to the restrictions in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, the draw of the Cermak Road bridge across the South Branch of the Chicago River, shall open on signal. The draws of the following bridges in Chicago shall open on signal if tended or within 30 minutes after notice is given to the City of Chicago Bridge Desk:

South Branch

Randolph Street
Washington Street
Madison Street
Monroe Street
Adams Street
Jackson Boulevard
Van Buren Street
Congress Street (Eisenhower Expressway)
Harrison Street
Roosevelt Road
Eighteenth Street
Canal Street
South Halsted Street
South Loomis Street

West Fork of the South Branch

South Ashland Avenue
South Damen Avenue

Chicago River, North Branch

Division Street
Grand Avenue
Chicago Avenue
North Halsted Street

(2) From December 1 through March 31, the draws of the highway bridges across the Chicago River, the North Branch of the Chicago River, and the South Branch of the Chicago River shall open on signal if at least 12 hours notice is given. However, the bridges need not open during those periods of time specified in paragraphs (a)(1)(i), (ii) and (iii) of this section.

(b) For recreational vessels:

(1) From April 1 through November 30—

(i) The draws shall be scheduled to open, before 1 p.m., twice on Saturdays and twice on Sundays if requests for passage have been received at least 20 hours in advance. If the bridges have been authorized to remain closed for portions of a Saturday or Sunday to accommodate special events, openings shall be scheduled after 1 p.m. as necessary to provide two openings per day.

(ii) The draws shall open on Monday and Friday, after 6:30 p.m. Each opening requires notice that has been given at least 6 hours in advance of a vessel's requested time of passage.

(iii) The draws shall open on Wednesdays at 10 a.m., or as soon thereafter as practical, if a request for passage has been given at least 20 hours in advance.

(iv) The draws shall open at times in addition to those listed in paragraphs (b)(1)(i) through (b)(1)(iii) of this section, after notice has been given at least 20 hours in advance requesting passage for a flotilla of at least five vessels. However, the bridges need not open during those periods of time specified in paragraphs (a)(1) (i), (ii) and (iii) of this section.

(2) From December 1 through March 31, the draws of the highway bridges across the Chicago River, the North Branch of the Chicago River, and the South Branch of the Chicago River need open on signal only if at least 48 hours notice is given. However, the bridges need not open during those periods of time specified in (a)(1) (i), (ii) and (iii) of this section.

(3) Paragraph (b) of this section applies to the following listed bridges:

Main Branch

Lake Shore Drive
Columbus Drive
Michigan Avenue
Wabash Avenue
State Street
Dearborn Street
Clark Street
LaSalle Street
Wells Street
Franklin-Orleans St.

South Branch

Lake Street
Randolph Street
Washington Street
Monroe Street
Madison Street
Adams Street
Jackson Boulevard
Van Buren Street
Eisenhower Expressway
Harrison Street
Roosevelt Road
18th Street
Canal Street
South Halsted Street
South Loomis Street
South Ashland Avenue

North Branch

Grand Avenue
Ohio Street
Chicago Avenue
N. Halsted St.

(c) The following bridges need not be opened for the passage of vessels: The draws of the North Avenue, Cortland Street, Webster Avenue, North Ashland Avenue, Chicago and Northwestern Railroad, and North Damen Avenue

bridges across the North Branch of the Chicago River, and the draws of the N. Halsted St. bridge, the Division St. bridge and the Chicago, Milwaukee, St. Paul and Pacific Railroad bridge across the North Branch Canal.

(d) The opening signal for all Chicago River bridges is three short blasts or by shouting, except that four short blasts is the opening signal for the Chicago and Northwestern railroad bridge near Kinzie Street and the Milwaukee Road bridge near North Avenue and five short blasts is the opening signal for the Lake Shore bridge when approaching from the north.

(e) The emergency provisions of § 117.31 of this part apply to the passage of all vessels and the operation of all bridges on the Chicago River.

Dated: October 2, 1995.

G.F. Woolever,

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

[FR Doc. 95–24916 Filed 10–4–95; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–5309–5]

Clean Air Act Promulgation of Extension of Attainment Date for PM–10 Nonattainment Area in Denver, CO

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This action serves to grant a 1-year attainment date extension for the Denver, Colorado particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM–10) nonattainment area. This action is based on monitored air quality data for the national ambient air quality standard for PM–10 during the years 1992–94 and EPA's evaluation of the applicable state implementation plan (SIP).

DATES: This final rule is effective on December 5, 1995, unless adverse comments are received by November 6, 1995. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Comments should be addressed to: Douglas M. Skie, Chief, Air Programs Branch, EPA Region VIII, at the address listed below. Copies of the State's submittal and other information are available for inspection during normal business hours at the following locations: Air Programs Branch, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202–2405; and Colorado Air Pollution Control Division, 4300 Cherry Creek Drive South, Denver, Colorado 80222–1530. The information may be inspected between 8 a.m. and 4 p.m., on weekdays, except for legal holidays. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Callie Videtich, 8ART–AP, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202–2405, (303) 293–1754.

SUPPLEMENTARY INFORMATION:

I. Background

A. Clean Air Act Requirements and EPA Actions Concerning Designation and Classification

On the date of enactment of the 1990 Clean Air Act Amendments, PM–10 areas meeting the qualifications of section 107(d)(4)(B) of the Act were designated nonattainment by operation of law (see generally, 42 U.S.C. section 7407(d)(4)(B)). These areas included all former Group I areas identified in 52 FR 29383 (August 7, 1987) and further clarified in 55 FR 45799 (October 31, 1990), and any other areas violating the PM–10 standards prior to January 1, 1989 (many of these areas were identified by footnote 4 in the October 31, 1990 Federal Register notice). A Federal Register notice announcing the areas designated nonattainment for PM–10 upon enactment of the Act was published in 56 FR 11101 (March 15, 1991). A subsequent Federal Register notice correcting some of these areas was published on August 8, 1991 (56 FR 37654). These nonattainment designations and moderate area classifications were codified in 40 CFR part 81 in a Federal Register notice published on November 6, 1991 (56 FR 56694). All other areas in the Nation not designated nonattainment at enactment were designated unclassifiable (see section 107(d)(4)(B)(iii) of the Act). Additional PM–10 areas were designated nonattainment in subsequent Federal Register actions.

States containing areas which were designated as moderate nonattainment by operation of law under section 107(d)(4)(B) were to develop and submit SIPs to provide for the attainment of the PM–10 NAAQS. Pursuant to section 189(a)(2), those SIP revisions were to be submitted within one year of enactment of the Act (November 15, 1991). The SIP revisions were to provide for implementation of RACM/RACT by December 10, 1993 and attainment by December 31, 1994.

B. Application for a 1-Year Extension of the Attainment Date

If the State does not have the necessary number of consecutive clean years of data to show attainment of the NAAQS, a State may apply for an extension of the attainment date. Pursuant to section 188(d) of the Act, a State may apply for, and EPA may grant, a 1-year extension of the attainment date if the State has: (1) complied with the requirements and commitments pertaining to the applicable implementation plan for the area; and (2) the area has measured no more than one exceedance of the 24 hour PM–10 standard in the year preceding the extension year, and the annual mean concentration of PM–10 in the area for such year is less than or equal to the standard. If the State does not have the requisite number of years of clean air quality data to show attainment and does not apply or does not qualify for an attainment date extension, the area will be reclassified as serious by operation of law.

The authority delegated to the Administrator to extend attainment dates for moderate areas is discretionary. Section 188(d) of the Act provides that the Administrator ''may'' extend the attainment date for areas that meet the minimum requirements specified above. The provision does not dictate or compel that EPA grant extensions to such areas. In exercising this discretionary authority for PM–10 nonattainment areas, EPA will examine the air quality planning progress made in the moderate areas. EPA will be disinclined to grant an attainment date extension unless a State has, in substantial part, addressed its moderate PM–10 planning obligations for the area. In order to determine whether the State has substantially met these planning requirements, the EPA will review the State's application for the attainment date extension to determine: (1) Whether the State has adopted and substantially implemented control measures submitted to address the requirement for implementing RACM/RACT in the moderate nonattainment area; and (2) that reasonable further progress is being met for the area. RFP for PM–10 nonattainment areas is determined to be linear emissions reductions made on an annual basis which will provide progress toward the eventual attainment of the NAAQS in the area. If the State cannot make a sufficient demonstration that the area has complied with the extension criteria

stated above, and EPA determines that the area has not demonstrated attainment of the PM–10 NAAQS, the area will be reclassified as serious by operation of law pursuant to section 188(b) of the Act. If an extension is granted, at the end of the extension year, EPA will again determine whether the area has attained the PM–10 NAAQS. If the requisite 3 consecutive years of clean air quality data needed to demonstrate attainment are not met, the State may apply for a second 1-year extension of the attainment date. In order to qualify for the second 1-year extension of the attainment date, the State must satisfy the same requirements listed above for the first extension. In addition, EPA will consider the State's PM–10 planning progress for the area in a manner similar to its evaluation of the first extension request. However, EPA may grant no more than two 1-year extensions of the attainment date to a single nonattainment area [see section 188(d) of the Act].

II. Area Being Granted a 1-Year Extension of the Attainment Date

EPA is granting a 1-year extension of the attainment date for the Denver, Colorado PM–10 nonattainment area. As discussed below and in the accompanying technical support document to this action, this determination is based upon air quality data which revealed violations of the PM–10 NAAQS during the years of 1992–94 and EPA's evaluation of the applicable SIP.

If a State containing a moderate PM–10 nonattainment area does not have 3 consecutive years of clean air quality data to demonstrate that the area has attained the PM–10 NAAQS, the State may apply for a 1-year extension of the attainment date. The EPA may extend the attainment date for 1 year only if the State submits an application for the affected nonattainment area satisfying the requirements discussed above. The following area qualifies for an attainment date extension:

A. Denver, Colorado

1. Review of the ambient data: Denver has experienced exceedances of the 24-hour PM–10 NAAQS on six separate days since 1987. Two exceedances were recorded in 1987 and four exceedances in the 1992/93 winter season. A violation of the *annual* PM–10 NAAQS has never occurred. Since no exceedances of the PM–10 NAAQS were recorded in 1994, the area meets one of the requirements to qualify for an attainment date extension under section 188(d).[1] Data requirements for purposes of making comparisons with the 24-hour and annual PM–10 NAAQS must be consistent with section 2.3 of 40 CFR part 50, appendix K.

2. Review of SIP planning progress and SIP implementation: The State of Colorado originally submitted the PM–10 SIP for Denver on June 7, 1993. On December 20, 1993 (58 FR 66326), EPA proposed to limitedly approve the control measures contained in the June 7, 1993 Denver PM–10 SIP. On the same date, EPA also proposed to conditionally approve the Denver PM–10 SIP based on the State's commitment to revise permit limitations at two sources (Purina Mill and Electron Corporation). EPA limitedly approved the control measures contained in the June 7, 1993 Denver PM–10 SIP on July 25, 1994 (59 FR 37698). EPA limitedly approved the control measures because they strengthened the PM–10 SIP for Denver by advancing the PM–10 air quality goal of the Act. In addition, because EPA questioned the contribution of secondary particulate emissions in the attainment demonstration, EPA did not take action on whether the June 7, 1993 SIP submittal attained the NAAQS or met the reasonably available control measures (RACM) (including reasonably available control technology (RACT)) requirements of the Act.

On March 30, 1995, the State of Colorado re-submitted the entire SIP for the Denver PM–10 nonattainment area. This revision is intended to satisfy the PM–10 SIP requirements that were due on November 15, 1991: i.e., provisions to assure that RACM/RACT would be implemented by December 10, 1993, a demonstration that the NAAQS will be attained, quantitative milestones which will be achieved every three years and which demonstrate reasonable further progress by December 31, 1994 and provisions to assure that the control requirements applicable to major stationary sources of PM–10 also apply to major stationary sources of PM–10 precursors. EPA is still evaluating the March 30, 1995 submittal and will determine, at a later date, whether the November 15, 1991 requirements are met in their entirety. Finally, the permits have been issued to Purina Mills and Electron Corporation, fulfilling the State's earlier commitments.

Pursuant to EPA's November 14, 1994 guidance entitled ''Criteria for Granting 1-Year Extensions of Moderate PM–10 Nonattainment Area Attainment Dates, Making Attainment Determinations, and Reporting on Quantitative Milestones,'' from Sally Shaver, Director of Air Quality Strategies and Standards Divisions, to Regional Air Division Directors, ''[t]he State must demonstrate that it has complied with all requirements and commitments pertaining to the affected nonattainment area in the applicable implementation plan.'' In addition, this guidance indicates that ''[i]n instances where EPA will not have taken final rulemaking action on the State's moderate area SIP revision prior to granting the attainment date extension for the area, the applicable SIP for the area would be the most recent federally approved particulate matter SIP for the area.'' Since EPA has not approved all portions of the PM–10 SIP for Denver, EPA also considered the State's total suspended particulate (TSP) SIP for the Denver area. EPA approved the Denver TSP SIP on October 5, 1979 (44 FR 57401). The TSP SIP control measures consisted of street cleaning practices, unpaved road controls, control of mud and dirt carry out sources, control of construction, grading, excavation, and demolition, and paving or stabilizing unpaved roads and alleys.

For the most part, the PM–10 SIP for Denver addresses the same type of emissions addressed in the TSP SIP. In addition, the PM–10 SIP is more stringent than the TSP SIP because the PM–10 SIP incorporates regulations that require a certain percentage of sand reductions on streets as well as street cleaning requirements and sand specification requirements. Also, the PM–10 SIP addresses other PM–10 emissions including woodburning. Although additional reentrained road dust requirements for a portion of the nonattainment area were submitted in March 30, 1995, for which EPA has not completed its review, EPA has approved the majority of the PM–10 SIP pertaining to reentrained road dust emissions. Therefore, since the PM–10 SIP, for the most part, supplants the TSP SIP for Denver, EPA believes it is more appropriate to evaluate the implementation of the PM–10 SIP and not the TSP SIP.

The State has completed its air quality planning requirements for the Denver PM–10 nonattainment area that were due by November 15, 1991. As indicated above, the State submitted a revised plan that supersedes and replaces all

[1] The Act states that no more than one exceedance may have occurred in the area [see section 189(d)(2)]. The EPA interprets this to prohibit extensions if there is more than one measured exceedance of the 24-hour standard at any monitoring site in the nonattainment area. The number of exceedances will not be adjusted to expected exceedances as long as the minimum required sampling frequencies have been met.

other versions of the Denver PM–10 SIP element. EPA is still evaluating this submittal. However, the March 30, 1995 SIP purports to demonstrate attainment of the NAAQS by December 31, 1994, and if this is the case, the State would have met its RACM/RACT requirements.

EPA has evaluated the milestone report submitted by the State on March 31, 1995, to determine the State's progress in implementing the Denver PM–10 SIP. As indicated earlier, the majority of the SIP was submitted in June 1993. The milestone report indicates that the State has implemented 100% of its originally adopted control measures. Therefore, EPA believes that the State has substantially implemented its RACM/RACT requirements and has made emission reductions amounting to reasonable further progress (RFP) toward attainment of the PM–10 NAAQS as defined in section 171(1) of the Act.

III. Final Action

EPA is granting a 1-year attainment date extension for the Denver, Colorado PM–10 nonattainment area. This action is based on monitored air quality data for the national ambient air quality standard for PM–10 during the years 1992–94 and EPA's evaluation of the applicable SIP. Therefore, the attainment date for the Denver, Colorado PM–10 nonattainment area is now December 31, 1995. If necessary, the State may request one more 1-year attainment date extension.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this Federal Register publication, EPA is proposing to approve the SIP revision should adverse or critical comments be submitted. Under the procedures established in the May 10, 1994 Federal Register (59 FR 24054), this action will be effective December 5, 1995 unless, by November 6, 1995, adverse or critical comments are received.

If such comments are received, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective on December 5, 1995.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to a SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

IV. Executive Order (EO) 12866

Under E.O. 12866, 58 FR 51735 (October 4, 1993), EPA is required to determine whether regulatory actions are significant and therefore should be subject to OMB review, economic analysis, and the requirements of the Executive Order. The Executive Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may meet at least one of the four criteria identified in section 3(f), including, under paragraph (1), that the rule may ''have an annual effect on the economy of $100 million or more or adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.''

The Agency has determined that the granting of attainment date extensions would result in none of the effects identified in section 3(f). Attainment date extensions under section 188(d) of the CAA do not impose any new requirements on any sectors of the economy; nor do they result in a materially adverse impact on State, local, or tribal governments or communities.

V. Regulatory Flexibility

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

Extension of nonattainment area attainment dates under section 188(b)(2) of the CAA do not create any new requirements. Therefore, because this federal approval does not impose any new requirements, I certify that it does not have a significant impact on small entities.

VI. Unfunded Mandates

Under sections 202, 203 and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must assess whether various actions undertaken in association with proposed or final regulations include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local or tribal governments in the aggregate.

EPA has determined, as discussed earlier in section IV. of this action, that this final action of granting a one-year extension to the Denver, Colorado PM–10 nonattainment area does not impose any federal intergovernment mandate, as defined in section 101 of the Unfunded Mandates Act. A finding that an area should be granted a one-year extension of the attainment date consists of factual determinations based upon air quality considerations and the area's compliance with certain prior requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector result from this action. This action also will not impose a mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector.

VII. Petition Language

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 December 5, 1995. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review must be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Dated: September 25, 1995.

Jack W. McGraw,

Acting Regional 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. 7401–7671q.

Subpart G—Colorado

2. Section 52.322 is added to read as follows:

§ 52.322 Extensions.

The Administrator, by authority delegated under section 188(d) of the Clean Air Act, as amended in 1990, extends for one year (until December 31, 1995) the attainment date for the Denver, Colorado, PM–10 nonattainment area.

[FR Doc. 95–24508 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 58

[FRL–5304–9]

RIN 2060–AF88

Ambient Air Quality Surveillance Siting Criteria for Open Path Analyzers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending its regulations to define the appropriate ambient air monitoring criteria for open path (long-path) analyzers. These revisions to the Ambient Air Quality Surveillance regulations define the siting requirements for open path analyzers used as State and Local Air Monitoring Stations (SLAMS), National Air Monitoring Stations (NAMS) and Photochemical Assessment Monitoring Stations (PAMS), as well as general quality assurance procedures for this technology. These changes provide the ambient air monitoring community with criteria needed to effectively use open path analyzers and associated data for regulatory purposes.

EFFECTIVE DATE: This final rule and all contained regulatory changes except for appendix D, section 2.2, are effective on October 6, 1995. The 40 CFR part 58, appendix D, section 2.2 requirements are not effective until the Office of Management and Budget approves the information requirements contained in them and the EPA publishes a document announcing their approval in the Federal Register.

ADDRESSES: Copies of the comments received on the notice of proposed rulemaking, supporting documentation, and the response to public comments document may be obtained from: Air Docket (LE–131), Attention: Docket Number A–93–44, U.S. Environmental Protection Agency, room M–1500, 401 M Street, SW., Washington, D.C. 20460. Docket Number A–93–44, containing supporting information used in developing these revised regulations, is available for public inspection and copying between 8:30 a.m. and 12 noon, and between 1:30 p.m. and 3:30 p.m., Monday through Friday, at the EPA's Air Docket Section at the address noted above. As provided in 40 CFR part 2, a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Lee Ann B. Byrd (919) 541–5367, Monitoring and Quality Assurance Group (MD–14), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

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I. Authority

Sections 110, 301(a), 313, and 319 of the Clean Air Act as amended 42 U.S.C. 7410, 7601(a), 7613, 7619.

II. Background

A new technique for monitoring pollutants in ambient air has been developed and introduced to the EPA. Instruments based on this new technique, called open path (or long-path) analyzers, use ultraviolet, visible, or infrared light to measure nitrogen dioxide (NO_2), ozone (O_3), carbon monoxide (CO), sulfur dioxide (SO_2), and other gaseous pollutant concentrations over a path of several meters up to several kilometers. The measurements obtained by these open path analyzers are path-integrated values from which path-averaged concentrations are obtained. In contrast, traditional point analyzers measure pollutant concentrations at one specific point by extracting an air sample from the atmosphere through an inlet probe.

Due to the fundamental difference in the measurement principles of open path and point analyzers, there may be tradeoffs in using each type of instrument for certain applications. Because of the ability of open path analyzers to measure pollutant concentrations over a path, these new techniques are expected to provide better spatial coverage, and thereby a better assessment of a general population's exposure to air pollutants for certain applications. However, due to this same path-averaging characteristic, open path analyzers could underestimate high pollutant concentrations at specific points within the measurement path for other ambient air monitoring situations. The applicability of either technique to a particular monitoring scenario is dependent on a number of factors including plume dispersion characteristics, monitoring location, pollutant of interest, population density, site topography, and monitoring objective. The EPA has considered these factors in evaluating the advantages and disadvantages of using open path analyzers for the various ambient air monitoring applications detailed in 40 CFR part 58.

The EPA has assessed the performance of an open path analyzer as candidate equivalent methods for measuring ozone, sulfur dioxide, and nitrogen dioxide under part 53. This open path analyzer was formally designated as an equivalent method for each of the three pollutants in a Federal Register notice, volume 60, number 84 on May 2, 1995. In parallel with this effort, the EPA developed these part 58 siting and quality assurance criteria for open path analyzers, which were published on August 18, 1994 as a notice of proposed rulemaking.

The intended purpose of these revisions to part 58 is to define first the conceptual framework of network design and siting which is equally relevant to open path and point types of ambient air monitoring sites, followed by the practical implications that flow from the conceptual approach. Comments received in response to the notice of proposed rulemaking have been carefully considered. Improvements to the network design and siting criteria were identified from these comments, and, as appropriate,

were incorporated into the regulatory text as detailed in this action. Copies of the specific EPA responses to each comment received are available in the docket as noted previously.

III. Discussion of Regulatory Revisions and Major Comments on Proposal

A. Section 58.1 Definitions

Today's action adds several new definitions to part 58 which are needed to clearly define the proposed new requirements for open path analyzers. Definitions for ''point analyzer'' and ''open path analyzer'' have been added to define these two types of automated instruments and to clarify the distinction between them, since the various new and existing requirements may apply to one or the other or both types of analyzers. A new definition for ''probe'' is added to specify the inlet where an air sample is extracted from the atmosphere for delivery to a sampler or point analyzer. Similarly, a new definition is added for ''monitoring path'' to describe the path in the atmosphere over which an open path analyzer measures and averages a pollutant concentration. Closely associated with the term ''monitoring path'' are new definitions for ''monitoring path length,'' to describe the scalar length of the monitoring path, and ''optical measurement path length,'' to describe the actual length of the optical beam of an open path instrument. The length of the optical beam may be two or more times the length of the monitoring path when one or more mirrors are used to cause the optical beam to pass through the monitoring path more than once. One public comment recommended changes to the language of the two former definitions to clarify the differences between path integrated values and path-averaged concentrations. The EPA concurs with this recommendation and clarifying language has been added.

To help describe the new requirements for data quality assessment procedures, the term ''effective concentration'' is defined. This term refers to the ambient concentration of a pollutant over the monitoring path that would be equivalent to a much higher concentration of the pollutant contained in a short calibration cell inserted into the optical beam of an open path analyzer during a precision test or accuracy audit. Specifically, effective concentration is defined as the actual concentration of the pollutant in the test cell multiplied by the ratio of the optical measurement path length of the test cell to the optical measurement path length of the atmospheric monitoring path. Also, when a calibration cell is inserted into the actual atmospheric measurement beam of an open path analyzer for a precision or accuracy test, the resulting measurement reading would be the sum of the pollutant concentration in the calibration cell and the pollutant concentration in the atmosphere. The atmospheric pollutant concentration must be measured separately and subtracted from the test measurement to produce a ''corrected concentration,'' which would be the true test result. Thus, the term ''corrected concentration'' is defined as the result of such a precision or accuracy assessment test after correction of the test measurement by subtracting the atmospheric pollutant concentration.

Finally, a formal definition of ''monitor'' is provided to clarify its use in the regulations as a generic term to refer to any type of ambient air analyzer or sampler that is acceptable for use in a SLAMS monitoring network under appendix C of this part. A monitor could thus be a point analyzer, an open path analyzer, or a sampler.

B. Appendix A—Quality Assurance Requirements for SLAMS

Appendix A describes both general quality assurance requirements applicable to SLAMS air monitoring as well as specific procedures for assessing the quality of the monitoring data obtained in SLAMS monitoring networks. While the general quality assurance requirements (in section 2) are directly applicable to open path analyzers without change, the more specific data quality assessment procedures (in section 3) must be modified somewhat to apply to open path analyzers. Accordingly, changes to these procedures are provided to incorporate appropriate data quality assessment tests applicable to open path monitoring instruments. To the extent possible, the new requirements are similar or parallel to the existing requirements for point analyzers.

For both the precision test (section 3.1) and the accuracy audit (section 3.2), the new requirements specify that an optical calibration or test cell containing a pollutant concentration standard must be inserted into the optical measurement beam of the open path analyzer. Both theory and testing indicate that the use of such a calibration or test cell is equivalent in accuracy to measurement of the equivalent pollutant concentration in air over the entire monitoring path of an open path analyzer. Each concentration standard must be selected such that it produces an ''effective concentration'' equivalent to a specified ambient concentration over the monitoring path. As noted previously, effective concentration is defined as the actual concentration of the pollutant in the test cell multiplied by the ratio of the optical measurement path length of the test cell to the optical measurement path length of the atmospheric monitoring path. The effective concentrations specified for the precision and accuracy tests for open path analyzers are the same as the test concentrations currently specified in these procedures for point analyzers.

Ideally, precision and accuracy assessments should test a monitoring instrument in its normal monitoring configuration. Therefore, the new test procedures require that the test or calibration cell containing the test pollutant concentration standard be inserted into the actual atmospheric measurement beam of the open path analyzer. The resulting test measurement of the pollutant concentration is thus the sum of the test concentration in the cell and the pollutant concentration in the atmosphere, because the measurement beam would pass through both the test cell and the atmospheric monitoring path. Accordingly, a correction for the atmospheric concentration is required to obtain the true test result. In the new procedures, the atmospheric pollutant concentration is measured immediately before and again immediately after the precision or accuracy test, and the average of these two measurements is subtracted from the test concentration measurement to produce a ''corrected concentration,'' which is reported as the test result. One comment was received regarding the former correction procedure which indicated a concern that a second, point analyzer would be needed to complete the accuracy audit and precision check procedures described in the proposal. The accuracy audit and precision check procedures defined in this action do not require the use of a second point analyzer. It is intended that the ambient air concentration measurements needed to correct the test readings would be obtained by the open path analyzer under test. The language of the procedures has been changed to clarify this requirement.

The corrected concentration reported for a precision or accuracy test may not be accurate if the atmospheric pollutant concentration changes during the test. When the ambient concentration is variable, the average of the pre- and post-test measurements may not be an accurate representation of the ambient pollutant concentration during the test.

The proposed test procedures recommend that these tests should be carried out, if possible, during periods when the atmospheric pollutant concentration is low and steady. The lower the atmospheric pollutant concentration, the steadier the concentration is likely to be and the better the pre- and post-test measurements will represent the actual atmospheric concentration during the test measurement. Further, the procedures provide that if the pre- and post-test measurements of the atmospheric concentration differ by more than 20 percent of the effective concentration of the test standard, the test result is discarded and the test repeated.

Two comments were received regarding the recommendation that pre- and post-test measurements be taken when the atmospheric pollutant concentration is low and steady, such as during early morning or late evening hours. These comments illustrated a concern that it may be difficult for a monitoring agency to conduct the accuracy audits and precision checks at such specific times. In amending the monitoring regulations to permit the use of open path analyzers, the EPA is not suggesting that the use of open path analyzers is necessarily cost effective or even necessarily advantageous. The EPA is permitting their use, at the discretion of the monitoring agency, for whatever benefit the agency may believe to accrue. The recommendation cited is intended to point out that the precision and accuracy test results may be better if carried out during periods when concentration levels are more likely to be low and steady, and therefore the timing of these tests as to the time of day or the meteorological conditions of the day should be considered—to the extent practicable—by the monitoring agency scheduling these tests.

A comment was received which recommended that accuracy limits on the measurement of the optical measurement path length be incorporated into the regulation. This issue of the determination of the optical measurement path length is particularly important because an error in this parameter would not normally be compensated for in the calibration or be evident in the results of the accuracy audit procedures for open path analyzers. Therefore, the accuracy audit procedure has been revised to include reverification of this parameter.

It is recognized that the new tests for precision and accuracy for open path analyzers, as well as the existing tests for point analyzers, are described in very general terms, and that additional, more detailed information and guidance are usually necessary for an analyzer operator to carry out these tests properly. Accordingly, section 3 of appendix A is amended by adding an explicit indication that supplemental information and guidance to assist the analyst in conducting these tests may be available in the publication, ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II'' (EPA–600/4–77–027a, identified as Reference 3 at the end of appendix A), or in the operation or instruction manual associated with the particular monitor being used.

The techniques for precision and accuracy assessment of open path analyzers are based largely on consultations with the manufacturer, along with EPA tests, of the differential optical absorption spectrometer that is currently under consideration by the EPA for possible designation as equivalent methods under 40 CFR part 53. However, it is desirable that the techniques be generic in nature, if possible, so that they would be applicable to other types of open path monitoring instruments as well. In addition, for some types of open path instruments or for some installations or configurations, there may be technical reasons why the new techniques for precision and accuracy assessment may not be feasible, appropriate, or advisable. As a result, these procedures allow for the use of an alternate local light source or an alternate optical path that does not include the normal atmospheric monitoring path, if such an alternate configuration is permitted by the operation or instruction manual associated with the analyzer. Since the analyzer operation or instruction manual would be subject to approval as part of the requirements for EPA designation of an open path analyzer as an equivalent method, the EPA would thereby have control over the alternate configurations that would be allowable for the precision and accuracy assessment tests.

One comment was received recommending more details be provided within the regulation defining the limitations and conditions under which an alternative light source could be used. Because it is impossible to anticipate the variety of open path analyzers and audit techniques that could eventually be used, it is difficult, if not impossible, to define specific limits and conditions under which an alternative light source could be permitted for accuracy audits and precision checks. The specific authorization to use an alternate light source will be determined on a case-by-case basis for each specific open path analyzer subject to an equivalent method determination under part 53. Then, if permitted, the analyzer-specific conditions and limitations for its use would be described in detail in the associated operation/instruction manual. This manual is approved as part of the formal designation of the analyzer as an equivalent method, and the EPA can make sure that the procedures and conditions are addressed adequately in the manual before a candidate method is designated as an equivalent method.

C. Appendix B—Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring

Appendix B sets forth both general quality assurance requirements for PSD monitoring as well as specific procedures for assessing the quality of the monitoring data obtained in PSD monitoring networks. The amendments and procedures proposed for appendix B to extend the existing requirements to open path analyzers are essentially identical to the changes proposed for appendix A. Similarly, changes to the regulatory language resulting from public comments received on appendix A apply equally to appendix B.

D. Appendix D—Network Design for State and Local Air Monitoring Stations (SLAMS), National Air Monitoring Stations (NAMS), and Photochemical Air Monitoring Stations (PAMS)

Changes to appendix D were not recommended with the original proposal associated with this action. Public comments indicated the need for the EPA to consider the comparability of data collected by point analyzers and data collected by open path analyzers, particularly in situations of nonuniform pollutant concentrations. This issue also raises an additional concern over introducing new ambient air monitoring technologies into the Nation's monitoring program which is currently based on traditional point-specific monitoring techniques, and its impact on existing air quality management programs.

In response to these issues, the EPA has modified appendix D with criteria and requirements intended to help agencies determine what, if any, impacts the introduction of this technology may have on their local air quality management programs. These criteria include investigations into the specific technology selected for a chosen application, the site location with respect to the monitoring objective, and a requirement for concurrent

monitoring when replacing an existing monitor with one using a different ambient air monitoring technique. The intent of the latter requirement is to provide a bridge between the two types of ambient air monitoring data (point and path-averaged values).

The EPA recognizes that these appendix D requirements can be more effectively and efficiently used to improve an ambient air monitoring network if consideration for the particular monitoring site, objective, and related conditions is included in the network analysis. As a result, these requirements are presented in general terms, with waiver provisions provided as appropriate.

E. Appendix E—Probe and Path Siting Criteria for Ambient Air Quality Monitoring

This action amends appendix E by adding new siting criteria applicable to open path analyzers for monitoring of SO_2, O_3, NO_2, CO, and O_3 precursors (defined in the PAMS program as volatile organic compounds, oxides of nitrogen, and selected carbonyls). Because of the substantial similarity in the siting criteria for SO_2, O_3, and NO_2 (both the existing criteria for point monitors and proposed new criteria for open path analyzers), the siting requirements for these three pollutants are combined, consolidated, and set forth in section 2 of appendix E. As a result, the existing criteria for SO_2, O_3, and NO_2 in sections 3, 5, and 6 are deleted, and those sections are reserved. As noted below, the criteria for CO monitoring are somewhat different, so they are retained in a separate section 4. Siting criteria for measuring O_3 and its precursors as part of a PAMS network are included in section 10. In all cases, the new open path provisions have been incorporated into the existing provisions, as appropriate.

The new open path siting requirements largely parallel the existing requirements for point analyzers, with the revised provisions applicable to either a ''probe'' (for point analyzers), a ''monitoring path'' (for open path analyzers), or both, as appropriate. Accordingly, criteria for the monitoring path of an open path analyzer are described for horizontal and vertical placement, spacing from minor sources, spacing from obstructions, spacing from trees, and spacing from roadways. The open path requirements apply to most of the monitoring path—generally 80 or 90 percent—but not to the entire monitoring path, to allow some needed flexibility in siting open path analyzers. For example, using the proposed 80 percent requirement, a monitoring path may be sited across uneven terrain, where up to 20 percent of the monitoring path may not fall within the proposed 3- to-15 meter specification for height above ground.

Two comments were received on the optical obstructions, or physical interferences (e.g., rain, snow, fog) criteria discussed in sections 2.3, 4.2, and 10.2 of the proposed rule. The specific open path analyzer currently under consideration for designation as an equivalent method calculates the level of uncertainty for each data value obtained based on several factors including diminished light levels due to optical obstructions. These uncertainty levels may be used to invalidate data that are outside of established error acceptance levels. Invalidating these data will have an effect on the data capture percentages, and potentially, on the database's ability to properly characterize air quality for a given region. Because of this possibility, recommendations for conducting analyses of obscuration potential and its resulting effect on the representativeness of the data record have been included in sections 2.3, 4.2, and 10.2 of appendix E.

In addition to the criteria common to both point and open path analyzers mentioned above, two new provisions, applicable only to open path analyzers, are included which limit the maximum length of the monitoring path and the cumulative interferences on the path. The maximum monitoring path length limit helps to ensure that open path monitoring data represent the air volume that they are intended to measure according to the monitoring objectives of the spatial scale identified for the site. Similarly, the limit for the cumulative interferences on the monitoring path controls the total amount of interference from minor sources, roadways, obstructions, and other factors that might unduly influence the monitoring data collected by an open path analyzer. This limit is necessary because a long monitoring path presents a much greater opportunity to be affected by multiple interferences.

In the consolidation of current sections 3, 5, and 6 to section 2, Tables 2 and 3, which list the minimum separation distances between O_3 and NO_2 stations and nearby roadways, are combined and redesignated as Table 1. As a result, Table 1 (in section 3), Table 4 (in section 7), Table 5 (in section 10), and Table 6 (in section 12) are renumbered as Tables 2, 3, 4, and 5, respectively. Finally, the summary of all the general siting requirements in renumbered Table 5 is modified to include the new criteria for monitoring paths.

IV. Administrative Requirements

A. Administrative Designation

1. Executive Order 12866

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)) the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and to the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations or recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

2. Enhancing the Intergovernmental Partnership Under Executive Order 12875

In compliance with Executive Order 12875, we have involved State and local governments in the development of this rule. To accomplish this effort, we have presented information on the new open path analyzer technology at various national and international technical symposiums, such as the Air and Waste Management Association specialty conferences, which were attended by several State and local agencies. We have presented information and solicited comment from State and local ambient air monitoring agencies on the use of this new technology and the contents of this rule through forums such as the Standing Air Monitoring Work Group. This work group, which consists of various State and local agency and EPA representatives, is designed to provide a strategic vision and direction for the ambient air monitoring programs within the nation.

In evaluating open path analyzers, we have conducted joint methodology experiments in various locations with the States of Connecticut, Georgia, Florida, and Texas.

B. Reporting and Recordkeeping Requirements

The information collection requirements contained in this rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request document has been prepared by the EPA (ICR No. 0940.12) and a copy may be obtained from Sandy Farmer, Information Policy Branch, EPA, 401 M Street S.W., Mail Code 2136, Washington, D.C. 20460; or by calling (202) 260–2740. These requirements are not effective until OMB approves them and a technical amendment to that effect is published in the Federal Register.

This collection of information has an estimated reporting burden averaging 300 hours per response and an estimated annual recordkeeping burden averaging 24 hours per respondent. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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, EPA, 401 M Street S.W., Mail Code 2136, Washington, D.C. 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503, marked ''Attention: Desk Officer for EPA.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rulemaking package does not impose any additional requirements on small entities, rather, it is this action's intent to provide all entities with the option to choose the most suitable ambient air method for their particular application. This proposal provides the appropriate siting and quality assurance criteria for a new ambient air monitoring technology (open path analyzers) as they are used in various applications. The criteria listed in this rulemaking package parallel existing requirements and vary only as necessary due to technological differences between measurement techniques. It is possible that a beneficial impact may be encountered by some small entities that use this new technology in certain scenarios.

D. Unfunded Mandates Reform Act of 1995

Under sections 202, 203 and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, the EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local, or tribal governments in the aggregate.

The EPA's final action does not impose any federal intergovernmental mandate, as defined in section 101 of the Unfunded Mandates Act, upon any State, local, or tribal government. This action gives these entities an opportunity to choose the most suitable ambient air quality monitoring method for their program, but does mandate any particular method. Finally, the EPA has determined that this action does not include a mandate that may result in estimated costs of $100 million or more to State, local, or tribal governments in the aggregate. This action does not directly affect the private sector.

List of Subjects in 40 CFR Part 58

Environmental Protection, Air pollution control, Ambient air monitoring, Ambient air pollutant measurements, Ambient air monitoring networks and siting criteria, Ambient data, Intergovernmental relations, National ambient air monitoring program, Open path analyzers, Optical sensing, Quality assurance requirements, Reporting and recordkeeping requirements, State and local agency ambient air monitoring programs.

Dated: September 21, 1995.

Carol M. Browner,

Administrator.

For reasons set forth in the preamble, title 40, chapter I, part 58 of the Code of Federal Regulations is amended as follows:

PART 58—[AMENDED]

1. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7410, 7601(a), 7613, and 7619.

2. In § 58.1 paragraphs (aa) through (ii) are added to read as follows:

§ 58.1 Definitions.

* * * * *

(aa) *Point analyzer* is an automated analytical method that measures pollutant concentration in an ambient air sample extracted from the atmosphere at a specific inlet probe point and that has been designated as a reference or equivalent method in accordance with part 53 of this chapter.

(bb) *Probe* is the actual inlet where an air sample is extracted from the atmosphere for delivery to a sampler or point analyzer for pollutant analysis.

(cc) *Open path analyzer* is an automated analytical method that measures the average atmospheric pollutant concentration in situ along one or more monitoring paths having a monitoring path length of 5 meters or more and that has been designated as a reference or equivalent method under the provisions of part 53 of this chapter.

(dd) *Monitoring path* for an open path analyzer is the actual path in space between two geographical locations over which the pollutant concentration is measured and averaged.

(ee) *Monitoring path length* of an open path analyzer is the length of the monitoring path in the atmosphere over which the average pollutant concentration measurement (path-averaged concentration) is determined. See also, optical measurement path length.

(ff) *Optical measurement path length* is the actual length of the optical beam over which measurement of the pollutant is determined. The path-integrated pollutant concentration measured by the analyzer is divided by the optical measurement path length to determine the path-averaged concentration. Generally, the optical measurement path length is:

(1) Equal to the monitoring path length for a (bistatic) system having a transmitter and a receiver at opposite ends of the monitoring path;

(2) Equal to twice the monitoring path length for a (monostatic) system having a transmitter and receiver at one end of the monitoring path and a mirror or retroreflector at the other end; or

(3) Equal to some multiple of the monitoring path length for more complex systems having multiple passes of the measurement beam through the monitoring path.

(gg) *Effective concentration* pertains to testing an open path analyzer with a high-concentration calibration or audit standard gas contained in a short test cell inserted into the optical measurement beam of the instrument. Effective concentration is the equivalent ambient-level concentration that would produce the same spectral absorbance

over the actual atmospheric monitoring path length as produced by the high-concentration gas in the short test cell. Quantitatively, effective concentration is equal to the actual concentration of the gas standard in the test cell multiplied by the ratio of the path length of the test cell to the actual atmospheric monitoring path length.

(hh) *Corrected concentration* pertains to the result of an accuracy or precision assessment test of an open path analyzer in which a high-concentration test or audit standard gas contained in a short test cell is inserted into the optical measurement beam of the instrument. When the pollutant concentration measured by the analyzer in such a test includes both the pollutant concentration in the test cell and the concentration in the atmosphere, the atmospheric pollutant concentration must be subtracted from the test measurement to obtain the corrected concentration test result. The corrected concentration is equal to the measured concentration minus the average of the atmospheric pollutant concentrations measured (without the test cell) immediately before and immediately after the test.

(ii) *Monitor* is a generic term for an instrument, sampler, analyzer, or other device that measures or assists in the measurement of atmospheric air pollutants and which is acceptable for use in ambient air surveillance under the provisions of appendix C to this part, including both point and open path analyzers that have been designated as either reference or equivalent methods under part 53 of this chapter and air samplers that are specified as part of a manual method that has been designated as a reference or equivalent method under part 53 of this chapter.

3. Appendix A is amended as follows:

a. The fourth paragraph of section 3 introductory text is revised.

b. Section 3.1 is revised.

c. The text preceding the table in the second paragraph, and the seventh, and eighth paragraphs of section 3.2 are revised; and a new paragraph is added between the seventh and eighth paragraphs.

d. Table A–1 is revised.

Appendix A—Quality Assurance Requirements for State and Local Air Monitoring Stations (SLAMS)

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3. Data Quality Assessment Requirements

* * * * *

Assessment results shall be reported as specified in section 4. Concentration and flow standards must be as specified in sections 2.3 or 3.4. In addition, working standards and equipment used for accuracy audits must not be the same standards and equipment used for routine calibrations. Additional information and guidance in the technical aspects of conducting these tests may be found in Reference 3 or in the operation or instruction manual associated with the analyzer or sampler. Concentration measurements reported from analyzers or analytical systems (indicated concentrations) should be based on stable readings and must be derived by means of the same calibration curve and data processing system used to obtain the routine air monitoring data (see Reference 1 and Reference 3, section 2.0.9.1.3(d)). Table A–1 provides a summary of the minimum data quality assessment requirements, which are described in more detail in the following sections.

3.1 Precision of Automated Methods

A one-point precision check must be carried out at least once every two weeks on each automated analyzer used to measure SO_2, NO_2, O_3, and CO. The precision check is made by challenging the analyzer with a precision check gas of known concentration (effective concentration for open path analyzers) between 0.08 and 0.10 ppm for SO_2, NO_2, and O_3 analyzers, and between 8 and 10 ppm for CO analyzers. To check the precision of SLAMS analyzers operating on ranges higher than 0 to 1.0 ppm SO_2, NO_2, and O_3, or 0 to 100 ppm for CO, use precision check gases of appropriately higher concentration as approved by the appropriate Regional Administrator or the Regional Administrator's designee. However, the results of precision checks at concentration levels other than those specified above do not need be reported to the EPA. The standards from which precision check test concentrations are obtained must meet the specifications of section 2.3.

Except for certain CO analyzers described below, point analyzers must operate in their normal sampling mode during the precision check, and the test atmosphere must pass through all filters, scrubbers, conditioners, and other components used during normal ambient sampling and as much of the ambient air inlet system as is practicable. If permitted by the associated operation or instruction manual, a CO point analyzer may be temporarily modified during the precision check to reduce vent or purge flows, or the test atmosphere may enter the analyzer at a point other than the normal sample inlet, provided that the analyzer's response is not likely to be altered by these deviations from the normal operational mode.

If a precision check is made in conjunction with a zero or span adjustment, it must be made prior to such zero or span adjustments. Randomization of the precision check with respect to time of day, day of week, and routine service and adjustment is encouraged where possible.

Open path analyzers are tested by inserting a test cell containing a precision check gas concentration into the optical measurement beam of the instrument. If possible, the normally used transmitter, receiver, and, as appropriate, reflecting devices should be used during the test, and the normal monitoring configuration of the instrument should be altered as little as possible to accommodate the test cell for the test. However, if permitted by the associated operation or instruction manual, an alternate local light source or an alternate optical path that does not include the normal atmospheric monitoring path may be used. The actual concentration of the precision check gas in the test cell must be selected to produce an ''effective concentration'' in the range specified above. Generally, the precision test concentration measurement will be the sum of the atmospheric pollutant concentration and the precision test concentration. If so, the result must be corrected to remove the atmospheric concentration contribution. The ''corrected concentration'' is obtained by subtracting the average of the atmospheric concentrations measured by the open path instrument under test immediately before and immediately after the precision check test from the precision test concentration measurement. If the difference between these before and after measurements is greater than 20 percent of the effective concentration of the test gas, discard the test result and repeat the test. If possible, open path analyzers should be tested during periods when the atmospheric pollutant concentrations are relatively low and steady.

Report the actual concentration (effective concentration for open path analyzers) of the precision check gas and the corresponding concentration measurement (corrected concentration, if applicable, for open path analyzers) indicated by the analyzer. The percent differences between these concentrations are used to assess the precision of the monitoring data as described in section 5.1.

3.2 Accuracy of Automated Methods

* * * * *

The audit is made by challenging the analyzer with at least one audit gas of known concentration (effective concentration for open path analyzers) from each of the following ranges that fall within the measurement range of the analyzer being audited: * * *

* * * * *

For point analyzers, the audit shall be carried out by allowing the analyzer to analyze the audit test atmosphere in its normal sampling mode such that the test atmosphere passes through all filters, scrubbers, conditioners, and other sample inlet components used during normal ambient sampling and as much of the ambient air inlet system as is practicable. The exception provided in section 3.1 for certain CO analyzer does not apply for audits.

Open path analyzers are audited by inserting a test cell containing the various audit gas concentrations into the optical measurement beam of the instrument. If possible, the normally used transmitter, receiver, and, as appropriate, reflecting devices should be used during the audit, and the normal monitoring configuration of the instrument should be modified as little as possible to accommodate the test cell for the audit. However, if permitted by the associated operation or instruction manual, an alternate local light source or an alternate optical path that does not include the normal atmospheric monitoring path may be used. The actual concentrations of the audit gas in the test cell must be selected to produce ''effective concentrations'' in the ranges specified in this section 3.2. Generally, each audit concentration measurement result will be the sum of the atmospheric pollutant concentration and the audit test concentration. If so, the result must be corrected to remove the atmospheric concentration contribution. The ''corrected concentration'' is obtained by subtracting the average of the atmospheric concentrations measured by the open path instrument under test immediately before and immediately after the audit test (or preferably before and after each audit concentration level) from the audit concentration measurement. If the difference between the before and after measurements is greater than 20 percent of the effective concentration of the test gas standard, discard the test result for that concentration level and repeat the test for that level. If possible, open path analyzers should be audited during periods when the atmospheric pollutant concentrations are relatively low and steady. Also, the monitoring path length must be reverified to within ±3 percent to validate the audit, since the monitoring path length is critical to the determination of the effective concentration.

Report both the audit test concentrations (effective concentrations for open path analyzers) and the corresponding concentration measurements (corrected concentrations, if applicable, for open path analyzers) indicated or produced by the analyzer being tested. The percent differences between these concentrations are used to assess the accuracy of the monitoring data as described in section 5.2.

* * * * *

TABLE A–1.—MINIMUM DATA ASSESSMENT REQUIREMENTS

Method	Assessment method	Coverage	Minimum frequency	Parameters reported
Precision:				
Automated methods for SO_2, NO_2, O_3, and CO.	Response checks at concentration between .08 & .10 ppm (8 & 10 ppm for CO)[2].	Each analyzer	Once per 2 weeks	Actual concentration[2] & measured concentration.[3]
Manual methods including lead.	Collocated samplers	1 site for 1–5 sites; 2 sites for 6–20 sites; 3 sites> 20 sites (sites with highest conc.).	Once per week	Two concentration measurements.
Accuracy:				
Automated methods for SO_2, NO_2, O_3, and CO.	Response checks at: .03–.08 ppm;[1,2] .15–.20 ppm;[1,2] .35–.45 ppm;[1,2] .80–.90 ppm;[1,2] (If applicable).	1. Each analyzer. 2. 25% of analyzers (at least 1).	1. Once per year. 2. Each calendar quarter	Actual concentration[2] & measured (indicated) concentration[3] for each level.
Manual methods for SO_2 and NO_2.	Check of analytical procedure with audit standard solutions.	Analytical system	Each day samples are analyzed, at least twice per quarter.	Actual concentration & measured (indicated) concentration for each audit solution.
TSP, PM–10	Check of sampler flow rate	1. Each sampler. 2. 25% of samplers (at least 1).	1. Once per year. 2. Each calendar quarter	Actual flow rate and flow rate indicated by the sampler.
Lead	1. Check sample flow rate as for TSP. 2. Check analytical system with Pb audit strips.	1. Each sampler. 2. Analytical system	1. Include with TSP. 2. Each quarter	1. Same as for TSP. 2. Actual concentration & measured (indicated) concentration of audit samples (µg Pb/strip).

[1] Concentration times 100 for CO.
[2] Effective concentration for open path analyzers.
[3] Corrected concentration, if applicable, for open path analyzers.

* * * * *

4. Appendix B is amended as follows:

a. The first paragraph of section 3 is revised.

b. Section 3.1 is revised.

c. The text preceding the table in the first paragraph, and the third, and fourth paragraphs of section 3.2 are revised. A new paragraph is added between the third and fourth paragraphs.

d. Table B–1 is revised.

Appendix B—Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring

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3. Data Quality Assessment Requirements

All ambient monitoring methods or analyzers used in PSD monitoring shall be tested periodically, as described in this section 3, to quantitatively assess the quality of the data being routinely collected. The results of these tests shall be reported as specified in section 6. Concentration standards used for the tests must be as specified in section 2.3. Additional information and guidance in the technical aspects of conducting these tests may be found in Reference 3 or in the operation or instruction manual associated with the analyzer or sampler. Concentration measurements reported from analyzers or analytical systems must be derived by means of the same calibration curve and data processing system used to obtain the routine air monitoring data. Table B–1 provides a summary of the minimum data quality assessment requirements, which are described in more detail in the following sections.

3.1 Precision of Automated Methods

A one-point precision check must be carried out at least once every two weeks on each automated analyzer used to measure SO_2, NO_2, O_2, and CO. The precision check is made by challenging the analyzer with a precision check gas of known concentration (effective concentration for open path analyzers) between 0.08 and 0.10 ppm for SO_2, NO_2, and O_3 analyzers, and between 8 and 10 ppm for CO analyzers. The standards from which precision check test concentrations are obtained must meet the specifications of section 2.3. Except for certain CO analyzers described below, point analyzers must operate in their normal sampling mode during the precision check, and the test atmosphere must pass through all filters, scrubbers, conditioners and other components used during normal ambient sampling and as much of the ambient air inlet system as is practicable. If permitted by the associated operation or instruction manual, a CO point analyzer may be temporarily modified during the precision check to reduce vent or purge flows, or the test atmosphere may enter the analyzer at a point other than the normal sample inlet, provided that the analyzer's response is not likely to be altered by these deviations from the normal operational mode.

Open path analyzers are tested by inserting a test cell containing a precision check gas concentration into the optical measurement beam of the instrument. If possible, the normally used transmitter, receiver, and, as appropriate, reflecting devices should be used during the test, and the normal monitoring configuration of the instrument should be altered as little as possible to accommodate the test cell for the test. However, if permitted by the associated operation or instruction manual, an alternate local light source or an alternate optical path that does not include the normal atmospheric monitoring path may be used. The actual concentration of the precision check gas in the test cell must be selected to produce an ''effective concentration'' in the range specified above. Generally, the precision test concentration measurement will be the sum of the atmospheric pollutant concentration and the precision test concentration. If so, the result must be corrected to remove the atmospheric concentration contribution. The ''corrected concentration'' is obtained by subtracting the average of the atmospheric concentrations measured by the open path instrument under test immediately before and immediately after the precision check test from the precision test concentration measurement. If the difference between these before and after measurements is greater than 20 percent of the effective concentration of the test gas, discard the test result and repeat the test. If possible, open path analyzers should be tested during periods when the atmospheric pollutant concentrations are relatively low and steady.

If a precision check is made in conjunction with a zero or span adjustment, it must be made prior to such zero or span adjustment. The difference between the actual concentration (effective concentration for open path analyzers) of the precision check gas and the corresponding concentration measurement (corrected concentration, if applicable, for open path analyzers) indicated by the analyzer is used to assess the precision of the monitoring data as described in section 4.1. Report data only from automated analyzers that are approved for use in the PSD network.

3.2 Accuracy of Automated Methods

Each sampling quarter, audit each analyzer that monitors for SO_2, NO_2, O_3, or CO at least once. The audit is made by challenging the analyzer with at least one audit gas of known concentration (effective concentration for open path analyzers) from each of the following ranges that fall within the measurement range of the analyzer being audited:

* * *

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For point analyzers, the audit shall be carried out by allowing the analyzer to analyze the audit test atmosphere in the same manner as described for precision checks in section 3.1. The exception given in section 3.1 for certain CO analyzers does not apply for audits.

Open path analyzers are audited by inserting a test cell containing an audit gas concentration into the optical measurement beam of the instrument. If possible, the normally used transmitter, receiver, and, as appropriate, reflecting devices should be used during the audit, and the normal monitoring configuration of the instrument should be modified as little as possible to accommodate the test cell for the audit. However, if permitted by the associated operation or instruction manual, an alternate local light source or an alternate optical path that does not include the normal atmospheric monitoring path may be used. The actual concentrations of the audit gas in the test cell must be selected to produce ''effective concentrations'' in the range specified in this section 3.2. Generally, each audit concentration measurement result will be the sum of the atmospheric pollutant concentration and the audit test concentration. If so, the result must be corrected to remove the atmospheric concentration contribution. The ''corrected concentration'' is obtained by subtracting the average of the atmospheric concentrations measured by the open path instrument under test immediately before and immediately after the audit test (or preferably before and after each audit concentration level) from the audit concentration measurement. If the difference between these before and after measurements is greater than 20 percent of the effective concentration of the test gas standards, discard the test result for that concentration level and repeat the test for that level. If possible, open path analyzers should be audited during periods when the atmospheric pollutant concentrations are relatively low and steady. Also, the monitoring path length must be reverified to within ±3 percent to validate the audit, since the monitoring path length is critical to the determination of the effective concentration.

The differences between the actual concentrations (effective concentrations for open path analyzers) of the audit test gas and the corresponding concentration measurements (corrected

concentrations, if applicable, for open path analyzers) indicated by the analyzer are used to assess the accuracy of the monitoring data as described in section 4.2. Report data only from automated analyzers that are approved for use in the PSD network.

* * * * *

TABLE B–1.—MINIMUM PSD DATA ASSESSMENT REQUIREMENTS

Method	Assessment method	Coverage	Frequency	Parameters reported
Precision:				
Automated Methods for SO_2, NO_2, O_3, and CO.	Response check at concentration between .08 & .10 ppm (8 & 10 ppm for CO)[2].	Each analyzer	Once per 2 weeks	Actual concentration[2] & measured concentration.[3]
TSP, PM_{10}, Lead	Collocated samplers	Highest concentration site in monitoring network.	Once per week or every 3rd day for continuous sampling.	Two concentration measurements.
Accuracy:				
Automated Methods for SO_2, NO_2, O_3, and CO.	Response check at: .03–.08 ppm;[1,2] .15–.20 ppm;[1,2] .35–.45 ppm;[1,2] .80–.90 ppm;[1,2] (if applicable).	Each analyzer	Once per sampling quarter	Actual concentration[2] & measured (indicated) concentration[3] for each level.
TSP, PM_{10}	Sampler flow check	Each sampler	Once per sampling quarter	Actual flow rate and flow rate indicated by the sampler.
Lead	1. Sample flow rate check. 2. Check analytical system with Pb audit strips.	1. Each sampler. 2. Analytical system	1. Once/quarter. 2. Each quarter Pb samples are analyzed.	1. Same as for TSP. 2. Actual concentration & measured concentration of audit samples (μg Pb/strip).

[1] Concentration shown times 100 for CO.
[2] Effective concentration for open path analyzers.
[3] Corrected concentration, if applicable, for open path analyzers.

* * * * *

5. Appendix D is amended as follows:

a. The second, third, and fourth paragraphs of section 1 are revised; and a new paragraph is added between Table 1 and the last paragraph of section 1.

b. Section 2.2 is added.

Appendix D—Network Design for State and Local Air Monitoring Stations (SLAMS), National Air Monitoring Stations (NAMS), and Photochemical Assessment Monitoring Stations (PAMS)

1. SLAMS Monitoring Objectives and Spatial Scales

* * * * *

The network of stations which comprise SLAMS should be designed to meet a minimum of four basic monitoring objectives. These basic monitoring objectives are: (1) To determine highest concentrations expected to occur in the area covered by the network; (2) to determine representative concentrations in areas of high population density; (3) to determine the impact on ambient pollution levels of significant sources or source categories; and (4) to determine general background concentration levels. Of these four basic ambient air monitoring network design objectives, attempts to measure in areas of maximum concentrations and maximum population exposures (these can be exclusive or coincident) are primary due to the combination of prevailing needs and constraints.

It should be noted that this appendix contains no criteria for determining the total number of stations in SLAMS networks, except that a minimum number of lead SLAMS is prescribed. The optimum size of a particular SLAMS network involves tradeoffs between data needs and available resources which the EPA believes can best be resolved during the network design process.

This appendix focuses on the relationship between monitoring objectives and the geographical location of monitoring stations. Included are a rationale and set of general criteria for identifying candidate station locations in terms of physical characteristics which most closely match a specific monitoring objective. The criteria for more specifically siting the monitoring station, including spacing from roadways and vertical and horizontal probe and path placement, are described in appendix E of this part.

* * * * *

Open path analyzers can often be used effectively and advantageously to provide better monitoring representation for population exposure monitoring and general or background monitoring in urban and neighborhood scales of representation. Such analyzers may also be able to provide better area coverage or operational advantages in high concentration and source-impact monitoring in middle scale and possibly microscale areas. However, siting of open path analyzers for the latter applications must be carried out with proper regard for the specific monitoring objectives and for the path-averaging nature of these analyzers. Monitoring path lengths need to be commensurate with the intended scale of representativeness and located carefully with respect to local sources or potential obstructions. For short-term/high-concentration or source-oriented monitoring, the monitoring path may need to be further restricted in length and be oriented approximately radially with respect to the source in the downwind direction, to provide adequate peak concentration sensitivity. Alternatively, multiple (e.g., orthogonal) paths may be used advantageously to obtain both wider area coverage and peak concentration sensitivity. Further discussion on this topic is included in section 2.2 of this appendix.

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2. SLAMS Network Design Procedures

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2.2 Substantive Changes in SLAMS/NAMS Network Design Elements

Two important purposes of the SLAMS monitoring data are to examine and evaluate overall air quality within a certain region, and to assess the trends in air pollutant levels over several years. The EPA believes that one of the primary tools for providing these characterizations is an ambient air monitoring program which implements technically representative networks. The design of these networks must be carefully evaluated not only at their outset, but at relatively frequent intervals thereafter, using an appropriate combination of other important technical tools, including: dispersion and receptor modeling, saturation studies, point and area source emissions analyses, and meteorological assessments. The impetus for these subsequent reexaminations of monitoring network adequacy stems not only from the need to evaluate the effect that changes in the environment may pose, but also from the recognition that new and/or refined tools and techniques for use in impact assessments are continually emerging and available for application.

Substantiative changes to an ambient air monitoring network are both inevitable and necessary; however, any changes in any substantive aspect of an existing SLAMS network or monitoring site that might affect the continuity or comparability of pollutant measurements over time must be carefully and thoroughly considered. Such substantive changes would include cessation of monitoring at an existing site, relocation of an existing site, a change in the type of monitoring method used, any change in the probe or path height or orientation that might affect pollutant measurements, any significant changes in calibration procedures or standards, any significant change in operational or quality assurance procedures, any significant change in the sources or the character of the area in the vicinity of a monitoring site, or any other change that could potentially affect the continuity or comparability of monitoring data obtained before and after the change.

In general, these types of changes should be made cautiously with due consideration given to the impact of such changes on the network/site's ability to meet its intended goals. Some of these changes will be inevitable (such as when a monitoring site will no longer be available and the monitor must be relocated, for example). Other changes may be deemed necessary and advantageous, after due consideration of their impact, even though they may have a deleterious effect on the long-term comparability of the monitoring data. In these cases, an effort should be made to quantify, if possible, or at least characterize, the nature or extent of the effects of the change on the monitoring data. In all cases, the changes and all information pertinent to the effect of the change should be properly and completely documented for evaluation by trends analysts.

The introduction of open path methods to the SLAMS monitoring network may seem relatively straightforward, given the kinds of technical analyses required in this appendix. However, given the uncertainties attendant to these analyses and the critical nature and far-reaching regulatory implications of some sites in the current SLAMS network composed of point monitors, there is a need to 'bridge' between databases generated by these different candidate methods to evaluate and promote continuity in understanding of the historical representativeness of the database.

Concurrent, nominally collocated monitoring must be conducted in all instances where an open path analyzer is effectively intended to replace a criteria pollutant point monitor which meets either of the following:

1. Data collected at the site represents the maximum concentration for a particular nonattainment area; or

2. Data collected at the site is currently used to characterize the development of a nonattainment area State implementation plan.

The Regional Administrator, the Administrator, or their appropriate designee may also require collocated monitoring at other sites which are, based on historical technical data, significant in assessing air quality in a particular area. The term of this requirement is determined by the Regional Administrator (for SLAMS), Administrator (for NAMS), or their appropriate designee. The recommended minimum term consists of one year (or one season of maximum pollutant concentration) with a maximum term indexed to the subject pollutant NAAQS compliance interval (e.g., three calendar years for ozone). The requirement involves concurrent monitoring with both the open path analyzer and the existing point monitor during this term. Concurrent monitoring with more than one point analyzer with an open path analyzer using one or more measurement paths may also be advantageous to confirm adequate peak concentration sensitivity or to optimize the location and length of the monitoring path or paths.

All or some portion of the above requirement may be waived by the Regional Administrator (for SLAMS), the Administrator (for NAMS), or their designee in response to a request, based on accompanying technical information and analyses, or in certain unavoidable instances caused by logistical circumstances.

These requirements for concurrent monitoring also generally apply to situations where the relocation of any SLAMS site, using either a point monitor or an open path analyzer, within an area is being contemplated.

* * * * *

6. Appendix E is amended as follows:

a. The heading of appendix E is revised.

b. Section 1 is revised.

c. Section 2 is added and sections 3, 5, and 6 are removed and reserved.

d. Section 4 is revised.

e. In section 7, table 4 is redesignated as table 3.

f. The first paragraph of section 9 is revised.

g. Section 10 is revised.

h. Section 12 is revised.

Appendix E—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

1. Introduction

This appendix contains specific location criteria applicable to ambient air quality monitoring probes and monitoring paths after the general station siting has been selected based on the monitoring objectives and spatial scale of representation discussed in appendix D of this part. Adherence to these siting criteria is necessary to ensure the uniform collection of compatible and comparable air quality data.

The probe and monitoring path siting criteria discussed below must be followed to the maximum extent possible. It is recognized that there may be situations where some deviation from the siting criteria may be necessary. In any such case, the reasons must be thoroughly documented in a written request for a waiver that describes how and why the proposed siting deviates from the criteria. This documentation should help to avoid later questions about the validity of the resulting monitoring data. Conditions under which the EPA would consider an application for waiver from these siting criteria are discussed in section 11 of this appendix.

The spatial scales of representation used in this appendix, i.e., micro, middle, neighborhood, urban, and regional, are defined and discussed in

appendix D of this part. The pollutant-specific probe and monitoring path siting criteria generally apply to all spatial scales except where noted otherwise. Specific siting criteria that are phrased with a ''must'' are defined as requirements and exceptions must be approved through the waiver provisions. However, siting criteria that are phrased with a ''should'' are defined as goals to meet for consistency but are not requirements.

2. Sulfur dioxide (SO_2), Ozone (O_3), and Nitrogen Dioxide (NO_2)

Open path analyzers may be used to measure SO_2, O_3, and NO_2 at SLAMS/NAMS sites for middle, neighborhood, urban, and regional scale measurement applications. Additional information on SO_2, NO_2, and O_3 monitor siting criteria may be found in references 11 and 13.

2.1 Horizontal and Vertical Placement

The probe or at least 80 percent of the monitoring path must be located between 3 and 15 meters above ground level. The probe or at least 90 percent of the monitoring path must be at least 1 meter vertically or horizontally away from any supporting structure, walls, parapets, penthouses, etc., and away from dusty or dirty areas. If the probe or a significant portion of the monitoring path is located near the side of a building, then it should be located on the windward side of the building relative to the prevailing wind direction during the season of highest concentration potential for the pollutant being measured.

2.2 Spacing from Minor Sources (Applicable to SO_2 and O_3 Monitoring Only)

Local minor sources of SO_2 can cause inappropriately high concentrations of SO_2 in the vicinity of probes and monitoring paths for SO_2. Similarly, local sources of nitric oxide (NO) and ozone-reactive hydrocarbons can have a scavenging effect causing unrepresentatively low concentrations of O_3 in the vicinity of probes and monitoring paths for O_3. To minimize these potential interferences, the probe or at least 90 percent of the monitoring path must be away from furnace or incineration flues or other minor sources of SO_2 or NO, particularly for open path analyzers because of their potential for greater exposure over the area covered by the monitoring path. The separation distance should take into account the heights of the flues, type of waste or fuel burned, and the sulfur content of the fuel. It is acceptable, however, to monitor for SO_2 near a point source of SO_2 when the objective is to assess the effect of this source on the represented population.

2.3 Spacing From Obstructions

Buildings and other obstacles may possibly scavenge SO_2, O_3, or NO_2. To avoid this interference, the probe or at least 90 percent of the monitoring path must have unrestricted airflow and be located away from obstacles so that the distance from the probe or monitoring path is at least twice the height that the obstacle protrudes above the probe or monitoring path. Generally, a probe or monitoring path located near or along a vertical wall is undesirable because air moving along the wall may be subject to possible removal mechanisms. A probe must have unrestricted airflow in an arc of at least 270 degrees around the inlet probe, or 180 degrees if the probe is on the side of a building. This arc must include the predominant wind direction for the season of greatest pollutant concentration potential. A sampling station having a probe located closer to an obstacle than this criterion allows should be classified as middle scale rather than neighborhood or urban scale, since the measurements from such a station would more closely represent the middle scale. A monitoring path must be clear of all trees, brush, buildings, plumes, dust, or other optical obstructions, including potential obstructions that may move due to wind, human activity, growth of vegetation, etc. Temporary optical obstructions, such as rain, particles, fog, or snow, should be considered when siting an open path analyzer. Any of these temporary obstructions that are of sufficient density to obscure the light beam will affect the ability of the open path analyzer to continuously measure pollutant concentrations.

Special consideration must be devoted to the use of open path analyzers due to their inherent potential sensitivity to certain types of interferences, or optical obstructions. While some of these potential interferences are comparable to those to which point monitors are subject, there are additional sources of potential interferences which are altogether different in character. Transient, but significant obscuration of especially longer measurement paths could be expected to occur as a result of certain prevailing meteorological conditions (e.g., heavy fog, rain, snow) and/or aerosol levels that are of a sufficient density to prevent the open path analyzer's light transmission. If certain compensating measures are not otherwise implemented at the onset of monitoring (e.g., shorter path lengths, higher light source intensity), data recovery during periods of greatest primary pollutant potential could be compromised. For instance, if heavy fog or high particulate levels are coincident with periods of projected NAAQS-threatening pollutant potential, the representativeness of the resulting data record in reflecting maximum pollutant concentrations may be substantially impaired despite the fact that the site may otherwise exhibit an acceptable, even exceedingly high overall valid data capture rate.

In seeking EPA approval for inclusion of a site using an open path analyzer into the formal SLAMS/NAMS or PSD network, monitoring agencies must submit an analysis which evaluates both obscuration potential for a proposed path length for the subject area and the effect this potential is projected to have on the representativeness of the data record. This analysis should include one or more of the following elements, as appropriate for the specific circumstance: climatological information, historical pollutant and aerosol information, modeling analysis results, and any related special study results.

2.4 Spacing From Trees

Trees can provide surfaces for SO_2, O_3, or NO_2 adsorption or reactions and obstruct wind flow. To reduce this possible interference, the probe or at least 90 percent of the monitoring path should be 20 meters or more from the drip line of trees. If a tree or trees could be considered an obstacle, the probe or 90 percent of the monitoring path must meet the distance requirements of Section 2.3 and be at least 10 meters from the drip line of the tree or trees. Since the scavenging effect of trees is greater for O_3 than for other criteria pollutants, strong consideration of this effect must be given to locating an O_3 probe or monitoring path to avoid this problem.

2.5 Spacing From Roadways (Applicable to O_3 and NO_2 Only)

In siting an O_3 analyzer, it is important to minimize destructive interferences from sources of NO, since NO readily reacts with O_3. In siting NO_2 analyzers for neighborhood and urban scale monitoring, it is important to minimize interferences from automotive sources. Table 1 provides the required minimum separation distances between a roadway and a probe and between a roadway and at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A sampling station having a point analyzer probe located closer to a roadway than allowed by the Table 1 requirements

should be classified as middle scale rather than neighborhood or urban scale, since the measurements from such a station would more closely represent the middle scale. If an open path analyzer is used at a site, the monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For those situations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, one must consider the entire segment of the monitoring path in the area of potential atmospheric interference from automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and the minimum separation distance, as determined from Table 1. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

TABLE 1.—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND PROBES OR MONITORING PATHS FOR MONITORING NEIGHBORHOOD—AND URBAN—SCALE OZONE AND NITROGEN DIOXIDE

Roadway average daily traffic, vehicles per day	Minimum separation distance,[1] meters
≤10,000	10
15,000	20
20,000	30
40,000	50
70,000	100
≥110,000	250

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

2.6 Cumulative Interferences on a Monitoring Path

The cumulative length or portion of a monitoring path that is affected by minor sources, obstructions, trees, or roadways must not exceed 10 percent of the total monitoring path length.

2.7 Maximum Monitoring Path Length

The monitoring path length must not exceed 1 kilometer for analyzers in neighborhood, urban, or regional scale. For middle scale monitoring sites, the monitoring path length must not exceed 300 meters. In areas subject to frequent periods of dust, fog, rain, or snow, consideration should be given to a shortened monitoring path length to minimize loss of monitoring data due to these temporary optical obstructions. For certain ambient air monitoring scenarios using open path analyzers, shorter path lengths may be needed in order to ensure that the monitoring station meets the objectives and spatial scales defined for SLAMS in appendix D. Therefore, the Regional Administrator or the Regional Administrator's designee may require shorter path lengths, as needed on an individual basis, to ensure that the SLAMS meet the appendix D requirements. Likewise, the Administrator or the Administrator's designee may specify the maximum path length used at monitoring stations designated as NAMS or PAMS as needed on an individual basis.

* * * * *

4. Carbon Monoxide (CO)

Open path analyzers may be used to measure CO at SLAMS/NAMS sites for middle or neighborhood scale measurement applications. Additional information on CO monitor siting criteria may be found in reference 12.

4.1 Horizontal and Vertical Placement

Because of the importance of measuring population exposure to CO concentrations, air should be sampled at average breathing heights. However, practical factors require that the inlet probe be higher. The required height of the inlet probe for CO monitoring is therefore 3±½ meters for a microscale site, which is a compromise between representative breathing height and prevention of vandalism. The recommended 1 meter range of heights is also a compromise to some extent. For consistency and comparability, it would be desirable to have all inlets at exactly the same height, but practical considerations often prevent this. Some reasonable range must be specified and 1 meter provides adequate leeway to meet most requirements.

For the middle and neighborhood scale stations, the vertical concentration gradients are not as great as for the microscale station. This is because the diffusion from roads is greater and the concentrations would represent larger areas than for the microscale. Therefore, the probe or at least 80 percent of the monitoring path must be located between 3 and 15 meters above ground level for middle and neighborhood scale stations. The probe or at least 90 percent of the monitoring path must be at least 1 meter vertically or horizontally away from any supporting structure, walls, parapets, penthouses, etc., and away from dusty or dirty areas. If the probe or a significant portion of the monitoring path is located near the side of a building, then it should be located on the windward side of the building relative to both the prevailing wind direction during the season of highest concentration potential and the location of sources of interest, i.e., roadways.

4.2 Spacing from Obstructions

Buildings and other obstacles may restrict airflow around a probe or monitoring path. To avoid this interference, the probe or at least 90 percent of the monitoring path must have unrestricted airflow and be located away from obstacles so that the distance from the probe or monitoring path is at least twice the height that the obstacle protrudes above the probe or monitoring path. A probe or monitoring path located near or along a vertical wall is undesirable because air moving along the wall may be subject to possible removal mechanisms. A probe must have unrestricted airflow in an arc of at least 270 degrees around the inlet probe, or 180 degrees if the probe is on the side of a building. This arc must include the predominant wind direction for the season of greatest pollutant concentration potential. A monitoring path must be clear of all trees, brush, buildings, plumes, dust, or other optical obstructions, including potential obstructions that may move due to wind, human activity, growth of vegetation, etc. Temporary optical obstructions, such as rain, particles, fog, or snow, should be considered when siting an open path analyzer. Any of these temporary obstructions that are of sufficient density to obscure the light beam will affect the ability of the open path analyzer to continuously measure pollutant concentrations.

Special consideration must be devoted to the use of open path analyzers due to their inherent potential sensitivity to certain types of interferences, or optical obstructions. While some of these potential interferences are comparable to those to which point monitors are subject, there are additional sources of potential interferences which are altogether different in character. Transient, but significant obscuration of especially longer measurement paths could be expected to occur as a result of certain prevailing meteorological conditions (e.g., heavy fog, rain, snow) and/or aerosol levels that are of a sufficient density to prevent the open path analyzer's light transmission. If certain compensating measures are not otherwise implemented at the onset of monitoring (e.g., shorter path lengths, higher light source intensity), data recovery during periods of greatest primary pollutant potential could be compromised. For instance, if heavy fog or high particulate levels are coincident

with periods of projected NAAQS-threatening pollutant potential, the representativeness of the resulting data record in reflecting maximum pollutant concentrations may be substantially impaired despite the fact that the site may otherwise exhibit an acceptable, even exceedingly high overall valid data capture rate.

In seeking EPA approval for inclusion of a site using an open path analyzer into the formal SLAMS/NAMS or PSD network, monitoring agencies must submit an analysis which evaluates both obscuration potential for a proposed path length for the subject area and the effect this potential is projected to have on the representativeness of the data record. This analysis should include one or more of the following elements, as appropriate for the specific circumstance: climatological information, historical pollutant and aerosol information, modeling analysis results, and any related special study results.

4.3 Spacing From Roadways

Street canyon and traffic corridor stations (microscale) are intended to provide a measurement of the influence of the immediate source on the pollution exposure of the population. In order to provide some reasonable consistency and comparability in the air quality data from microscale stations, a minimum distance of 2 meters and a maximum distance of 10 meters from the edge of the nearest traffic lane must be maintained for these CO monitoring inlet probes. This should give consistency to the data, yet still allow flexibility of finding suitable locations.

Street canyon/corridor (microscale) inlet probes must be located at least 10 meters from an intersection and preferably at a midblock location. Midblock locations are preferable to intersection locations because intersections represent a much smaller portion of downtown space than do the streets between them. Pedestrian exposure is probably also greater in street canyon/corridors than at intersections. Also, the practical difficulty of positioning sampling inlets is less at midblock locations than at the intersection. However, the final siting of the monitor must meet the objectives and intent of appendix D, sections 2.4, 3, 3.3, and appendix E, section 4.

In determining the minimum separation between a neighborhood scale monitoring station and a specific line source, the presumption is made that measurements should not be substantially influenced by any one roadway. Computations were made to determine the separation distance, and table 2 provides the required minimum separation distance between roadways and a probe or 90 percent of a monitoring path. Probes or monitoring paths that are located closer to roads than this criterion allows should not be classified as a neighborhood scale, since the measurements from such a station would closely represent the middle scale. Therefore, stations not meeting this criterion should be classified as middle scale.

TABLE 2.—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND PROBES OR MONITORING PATHS FOR MONITORING NEIGHBORHOOD SCALE CARBON MONOXIDE

Roadway average daily traffic, vehicles per day	Minimum separation distance [1] for probes or 90% of a monitoring path (meters)
≤10,000	10
15,000	25
20,000	45
30,000	80
40,000	115
50,000	135
≤60,000	150

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

4.4 Spacing From Trees and Other Considerations

Since CO is relatively nonreactive, the major factor concerning trees is as obstructions to normal wind flow patterns. For middle and neighborhood scale stations, trees should not be located between the major sources of CO, usually vehicles on a heavily traveled road, and the monitor. The probe or at least 90 percent of the monitoring path must be 10 meters or more from the drip line of trees which are between the probe or the monitoring path and the road and which extend at least 5 meters above the probe or monitoring path. For microscale stations, no trees or shrubs should be located between the probe and the roadway.

4.5 Cumulative Interferences on a Monitoring Path

The cumulative length or portion of a monitoring path that is affected by obstructions, trees, or roadways must not exceed 10 percent of the total monitoring path length.

4.6 Maximum Monitoring Path Length

The monitoring path length must not exceed 1 kilometer for analyzers used for neighborhood scale monitoring applications, or 300 meters for middle scale monitoring applications. In areas subject to frequent periods of dust, fog, rain, or snow, consideration should be given to a shortened monitoring path length to minimize loss of monitoring data due to these temporary optical obstructions. For certain ambient air monitoring scenarios using open path analyzers, shorter path lengths may be needed in order to ensure that the monitoring station meets the objectives and spatial scales defined for SLAMS in appendix D. Therefore, the Regional Administrator or the Regional Administrator's designee may require shorter path lengths, as needed on an individual basis, to ensure that the SLAMS meet the appendix D requirements. Likewise, the Administrator or the Administrator's designee may specify the maximum path length used at monitoring stations designated as NAMS or PAMS as needed on an individual basis.

* * * * *

Table 3—Separation Distance Between Pb Stations and Roadways (Edge of Nearest Traffic Lane)

* * * * *

9. Probe Material and Pollutant Sample Residence Time

For the reactive gases, SO_2, NO_2, and O_3, special probe material must be used for point analyzers. Studies[20–24] have been conducted to determine the suitability of materials such as polypropylene, polyethylene, polyvinyl chloride, Tygon, aluminum, brass, stainless steel, copper, Pyrex glass and Teflon for use as intake sampling lines. Of the above materials, only Pyrex glass and Teflon have been found to be acceptable for use as intake sampling lines for all the reactive gaseous pollutants. Furthermore, the EPA[25] has specified borosilicate glass or FEP Teflon as the only acceptable probe materials for delivering test atmospheres in the determination of reference or equivalent methods. Therefore, borosilicate glass, FEP Teflon, or their equivalent must be used for existing and new NAMS or SLAMS.

* * * * *

10. Photochemical Assessment Monitoring Stations (PAMS)

10.1 Horizontal and Vertical Placement

The probe or at least 80 percent of the monitoring path must be located 3 to 15

meters above ground level. This range provides a practical compromise for finding suitable sites for the multipollutant PAMS. The probe or at least 90 percent of the monitoring path must be at least 1 meter vertically or horizontally away from any supporting structure, walls, parapets, penthouses, etc., and away from dusty or dirty areas.

10.2 Spacing From Obstructions

The probe or at least 90 percent of the monitoring path must be located away from obstacles and buildings such that the distance between the obstacles and the probe or the monitoring path is at least twice the height that the obstacle protrudes above the probe or monitoring path. There must be unrestricted airflow in an arc of at least 270° around the probe inlet. Additionally, the predominant wind direction for the period of greatest pollutant concentration (as described for each site in section 4.2 of appendix D) must be included in the 270° arc. If the probe is located on the side of the building, 180° clearance is required. A monitoring path must be clear of all trees, brush, buildings, plumes, dust, or other optical obstructions, including potential obstructions that may move due to wind, human activity, growth of vegetation, etc. Temporary optical obstructions, such as rain, particles, fog, or snow, should be considered when siting an open path analyzer. Any of these temporary obstructions that are of sufficient density to obscure the light beam will affect the ability of the open path analyzer to continuously measure pollutant concentrations.

Special consideration must be devoted to the use of open path analyzers due to their inherent potential sensitivity to certain types of interferences, or optical obstructions. While some of these potential interferences are comparable to those to which point monitors are subject, there are additional sources of potential interferences which are altogether different in character. Transient, but significant obscuration of especially longer measurement paths could be expected to occur as a result of certain prevailing meteorological conditions (e.g., heavy fog, rain, snow) and/or aerosol levels that are of a sufficient density to prevent the open path analyzer's light transmission. If certain compensating measures are not otherwise implemented at the onset of monitoring (e.g., shorter path lengths, higher light source intensity), data recovery during periods of greatest primary pollutant potential could be compromised. For instance, if heavy fog or high particulate levels are coincident with periods of projected NAAQS-threatening pollutant potential, the representativeness of the resulting data record in reflecting maximum pollutant concentrations may be substantially impaired despite the fact that the site may otherwise exhibit an acceptable, even exceedingly high overall valid data capture rate.

In seeking EPA approval for inclusion of a site using an open path analyzer into the formal SLAMS/NAMS or PSD network, monitoring agencies must submit an analysis which evaluates both obscuration potential for a proposed path length for the subject area and the effect this potential is projected to have on the representativeness of the data record. This analysis should include one or more of the following elements, as appropriate for the specific circumstance: climatological information, historical pollutant and aerosol information, modeling analysis results, and any related special study results.

10.3 Spacing From Roadways

It is important in the probe and monitoring path siting process to minimize destructive interferences from sources of NO since NO readily reacts with O_3. Table 4 below provides the required minimum separation distances between roadways and PAMS (excluding upper air measuring stations):

TABLE 4.—SEPARATION DISTANCE BETWEEN PAMS AND ROADWAYS

[Edge of Nearest Traffic Lane]

Roadway average daily traffic, vehicles per day	Minimum separation distance between roadways and stations in meters [1]
<10,000	>10
15,000	20
20,000	30
40,000	50
70,000	100
>110,000	250

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table based on the actual traffic flow.

10.4 Spacing From Trees

Trees can provide surfaces for adsorption and/or reactions to occur and can obstruct normal wind flow patterns. To minimize these effects at PAMS, the probe or at least 90 percent of the monitoring path should be placed at least 20 meters from the drip line of trees. Since the scavenging effect of trees is greater for O_3 than for the other criteria pollutants, strong consideration of this effect must be given in locating the PAMS probe or monitoring path to avoid this problem. Therefore, the probe or at least 90 percent of the monitoring path must be at least 10 meters from the drip line of trees.

* * * * *

12. Summary

Table 5 presents a summary of the general requirements for probe and monitoring path siting criteria with respect to distances and heights. It is apparent from Table 5 that different elevation distances above the ground are shown for the various pollutants. The discussion in the text for each of the pollutants described reasons for elevating the monitor, probe, or monitoring path. The differences in the specified range of heights are based on the vertical concentration gradients. For CO, the gradients in the vertical direction are very large for the microscale, so a small range of heights has been used. The upper limit of 15 meters was specified for consistency between pollutants and to allow the use of a single manifold or monitoring path for monitoring more than one pollutant.

TABLE 5.—SUMMARY OF PROBE AND MONITORING PATH SITING CRITERIA

Pollutant	Scale [maximum monitoring path length, meters]	Height from ground to probe or 80% of monitoring path [A] (meters)	Horizontal and vertical distance from supporting structures [B] to probe or 90% of monitoring path [A] (meters)	Distance from trees to probe or 90% of monitoring path [A] (meters)	Distance from roadways to probe or monitoring path [A] (meters)
SO_2 [C,D,E,F]	Middle [300m] Neighborhood, Urban, and Regional [1km].	3–15	>1	>10	N/A.
CO [D,E,G]	Micro Middle [300m] Neighborhood [1km].	3±0.5; 3–15	>1	>10	2–10; See Table 2 for middle and neighborhood scales.
O_3 [C,D,E]	Middle [300m] Neighborhood, Urban, and Regional [1km].	3–15	>1	>10	See Table 1 for all scales.
Ozone precursors (for PAMS) [C,D,E].	Neighborhood and Urban. [1 km]	3–15	>1	>10	See Table 4 for all scales.
NO_2 [C,D,E]	Middle [300m] Neighborhood and Urban [1km].	3–15	>1	>10	See Table 1 for all scales.
Pb [C,D,E,F,H]	Micro; Middle, Neighborhood, Urban and Regional.	2–7 (Micro); 2–15 (All other scales).	>2 (All scales, horizontal distance only).	>10 (All scales)	5–15 (Micro); See Table 3 for all other scales.
PM–10 [C,D,E,F,H]	Micro; Middle, Neighborhood, Urban and Regional.	2–7 (Micro); 2–15 (All other scales).	>2 (All scales, horizontal distance only).	>10 (All scales)	2–10 (Micro); See Figure 2 for all other scales.

N/A—Not applicable.

[A] Monitoring path for open path analyzers is applicable only to middle or neighborhood scale CO monitoring and all applicable scales for monitoring SO_2, O_3, O_3 precursors, and NO_2.

[B] When probe is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.

[C] Should be >20 meters from the dripline of tree(s) and must be 10 meters from the dripline when the tree(s) act as an obstruction.

[D] Distance from sampler, probe, or 90% of monitoring path to obstacle, such as a building, must be at least twice the height the obstacle protrudes above the sampler, probe, or monitoring path. Sites not meeting this criterion may be classified as middle scale (see text).

[E] Must have unrestricted airflow 270° around the probe or sampler; 180° if the probe is on the side of a building.

[F] The probe, sampler, or monitoring path should be away from minor sources, such as furnace or incineration flues. The separation distance is dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fuel (sulfur, ash, or lead content). This criterion is designed to avoid undue influences from minor sources.

[G] For microscale CO monitoring sites, the probe must be >10 meters from a street intersection and preferably at a midblock location.

[H] For collocated Pb and PM–10 samplers, a 2–4 meter separation distance between collocated samplers must be met.

* * * * *

[FR Doc. 95–24042 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Parts 60 and 61

[FRL–5310–9]

1993/1994 Updates for Delegation of Authority to Bernalillo County (New Mexico) for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Delegation of authority.

SUMMARY: The EPA announces the delegation of authority to the Albuquerque-Bernalillo County Air Quality Control Board (''the Board'') and the Albuquerque Environmental Health Department (AEHD) to implement and enforce the NSPS and NESHAP in Bernalillo County (New Mexico), including the City of Albuquerque. The provisions of full authority apply to all of the NSPS and NESHAP promulgated by the EPA through June 10, 1992 and August 31, 1993, for NSPS and June 3, 1992 and June 25, 1993, for NESHAP, and authority covers all new and amended standards promulgated after those dates. However, the delegation of authority, under this notice, does not apply to the sources located on Indian lands within the boundaries of Bernalillo County as specified in the delegation agreement and in this notice. Also, this delegation of authority is not applicable to the NESHAP radionuclide standards specified under 40 CFR part 61.

EFFECTIVE DATE: October 6, 1995.

ADDRESSES: The AEHD's request and delegation agreement may be obtained by writing to one of the following addresses: Mr. Thomas H. Diggs, Chief, Air Planning Section (6PD–L), U.S. Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202, telephone: (214) 665–7214; Mr. Steve Walker, Manager, Air Pollution Control Division, Albuquerque Environmental Health Department, The City of Albuquerque, P.O. Box 1293, Albuquerque, New Mexico 87103, telephone: (505) 768–2624.

FOR FURTHER INFORMATION CONTACT: Mr. Ken Boyce, Air Planning Section, U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202, telephone number (214) 665–7259.

SUPPLEMENTARY INFORMATION: Sections 111(c) and 112(l)(1) of the Clean Air Act allow the Administrator of the EPA to delegate the EPA's authority to any State or local agency which can submit adequate regulatory procedures for implementation and enforcement of the NSPS and NESHAP programs.

The New Mexico Air Quality Control Act (NMAQCA) allows, by ordinance, ''A'' class counties and any municipality within an ''A'' class county to create a municipal, county, or joint air quality board to administer and enforce the provisions of the NMAQCA. The City of Albuquerque and Bernalillo

County have jointly established the ''Albuquerque-Bernalillo County Air Quality Control Board'' (herein called ''the Board'') for administration and enforcement of NMAQCA because Bernalillo County is an ''A'' class county. Under the NMAQCA, the AEHD is the administrative and enforcement agency of the Board. The AEHD has established a program for the local administration and enforcement of the NMAQCA in Bernalillo County, in lieu of the New Mexico Environment Department (the State agency). Authority for the NSPS and NESHAP programs were delegated to the State of New Mexico (except for sources located in Bernalillo County and Indian lands) on March 15, 1985.

The Clean Air Act Amendments (CAAA) of 1990 required the EPA to make significant changes to the approach to delegation of section 112 requirements. Prior to the 1990 Amendments to the Clean Air Act (CAA), delegation of section 112 requirements could occur without the need for a rulemaking by EPA. However, the new section 112(l) of the Act requires the EPA to approve, through rulemaking, a program for delegation which includes delegation of Federal requirements incorporated by reference. The Title V Federal Register notice dated January 10, 1995, (pages 2531–2532) outlined the City's plans to continue to incorporate by reference the Federal section 112 requirements regarding hazardous air pollutants, into the City of Albuquerque/County of Bernalillo Air Quality Control Board Regulations and stated that the City's request for approval of the part 70 program is also a request for approval of a program for delegation of unchanged section 112 standards.

Based on approval of the procedural mechanism of the City of Albuquerque/County of Bernalillo for adoption of the Federal section 112 standards by incorporation by reference in the City's part 70 Operating Permit Program, the EPA can continue to update by letter the City's delegation of section 112 standards along with the update of the section 111 NSPS standards. In the future, the effective date of the delegation for unchanged Federal standards under section 112 will be the effective date of the State's rule after its adoption by the Air Quality Control Board. The effective date of the Federal delegation for NSPS standards under section 111 will continue to be, as has been the case in the past, the EPA letter of approval of the City's request for the NSPS delegation update.

On July 22, 1993, former Governor Bruce King and on June 6, 1995, the Director, AEHD, requested the EPA to update the delegation of authority to the AEHD for the NSPS and the NESHAP programs through June 10, 1992, and August 31, 1993, for NSPS and June 3, 1992, and June 25, 1993, for NESHAP. The AEHD also requested delegation of authority for the technical and administrative review of new or amended NSPS and NESHAP promulgated by the EPA after June 10, 1992, and August 31, 1993, for NSPS and June 3, 1992 and June 25, 1993, for NESHAP. The AEHD's request included:

(1) Air Quality Control Regulations (AQCR) 30 (NSPS) and 31 (NESHAP), (2) legal authority provided in Joint Air Quality Control Board Ordinances Article XVI and No. 88–45, and (3) the commitments for implementation and enforcement of the programs as documented in the July 22, 1993, Governor's letter and the AEHD Director's letter dated June 6, 1995. AQCR's 30 and 31 incorporate the Federal NSPS and NESHAP by reference through June 10, 1992, and August 31, 1993, for NSPS and June 3, 1992, and June 25, 1993, for NESHAP.

The EPA reviewed the AEHD Director's request, AQCR's 30 and 31, and all other information submitted by the AEHD, including its request for implementation of the delegation of these programs. The EPA has determined that the Board and the AEHD have adequate authority and effective procedures for implementing and enforcing the NSPS and NESHAP programs in Bernalillo County. Therefore, the EPA is delegating full authority to the Board and the AEHD through June 10, 1992, and August 31, 1993, for NSPS and June 3, 1992, and June 25, 1993, for NESHAP, and authority for the technical and administrative review of new or amended NSPS and NESHAP promulgated by the EPA after June 10, 1992, and August 31, 1993, for NSPS and June 3, 1992 and June 25, 1993, for NESHAP, subject to conditions and limitations of the delegation agreement dated December 8, 1989. It is important to note that no delegation authority is granted to the Board or AEHD for sources located on Indian lands within the boundaries of Bernalillo County. Also, no authority is delegated to the AEHD for 40 CFR part 60, subpart AAA, Standards of Performance for New Residential Wood Heaters, and for 40 CFR part 61 for the radionuclide NESHAP's. Specifically, the subparts for which delegation is excluded are subpart B (National Emission Standards for Radon—222 Emissions from Underground Uranium Mines), subpart H (National Emission Standards for Radionuclide Emissions from Department of Energy Facilities), subpart I (National Emission Standards for Radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities not covered by subpart H), subpart K—(National Emission Standards for Radionuclide Emissions from Elemental Phosphorus Plants), subpart R (National Emission Standards for Radon Emissions from Phosphogypsum Stacks), subpart T (National Emission Standards for Radon Emissions from the Disposal of Uranium Mill Tailings), and subpart W (National Emission Standards for Radon—222 Emissions from Licensed Uranium Mill Tailings).

Today's notice informs the public that the EPA has delegated full authority to the AEHD for implementation and enforcement of the NSPS and NESHAP promulgated by the EPA through June 10, 1992, and August 31, 1993, for NSPS and June 3, 1992, and June 25, 1993, for NESHAP, and authority is delegated for the new and amended standards after that date. All of the required information, pursuant to the Federal NSPS and NESHAP (40 CFR part 60 and 40 CFR part 61) by sources located within the boundaries of Bernalillo County and in areas outside of Indian lands, should be submitted directly to the Albuquerque Environmental Health Department, the City of Albuquerque, P.O. Box 1293, Albuquerque, New Mexico 87103. Sources located on Indian lands in the State of New Mexico, including Bernalillo County, should apply to the EPA Region 6 office at the address given in this notice. The sources located in the State of New Mexico, other than those areas specified above, should submit all of the required information to Chief, Air Quality Bureau, New Mexico Environment Department, 1190 St. Francis Drive, Santa Fe, New Mexico 87503. All of the inquiries and requests concerning implementation and enforcement of the excluded standards under 40 CFR part 60, subpart AAA and 40 CFR part 61, subpart B,H,I,R,T and W, in the State of New Mexico, should be directed to the EPA Region 6 office.

The Office of Management and Budget has exempted this information notice from the requirements of section 6 of Executive Order 12866.

This delegation is issued under the authority of section 111(c) and 112(l)(1) of the Clean Air Act, as amended (42 U.S.C. 7411(C) and 7412(D)).

List of Subjects

40 CFR Part 60

Air pollution control, Aluminum, Ammonium sulfate plants, Cement industry, Coal, Copper, Electric power plants, Fossil-fuel steam generators, Glass and glass products, Grain, Iron, Lead, Metals, Motor vehicles, Nitric acid plants, Paper and paper industry, Petroleum phosphate, Fertilizer, Sewage disposal, Steel, Sulfuric acid plants, Waste treatment and disposal, and Zinc.

40 CFR Part 61

Air pollution control, Asbestos, Benzene, Beryllium, Hazardous materials, Mercury, Vinyl chloride.

Dated: September 21, 1995.

Russell Rhoades,

Acting Regional Administrator.

[FR Doc. 95–24877 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Parts 60 and 61

[FRL–5310–8]

Approval of Delegation of Authority to the State of New Mexico for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Delegation of authority

SUMMARY: The EPA announces the delegation of authority to the State of New Mexico to implement and enforce the New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP). The provisions of full authority apply to all of the NSPS and NESHAP promulgated by the EPA from November 15, 1992, through February 1, 1995. Partial authority covers all new and amended standards promulgated after these dates, except as follows. The delegation of authority, under this notice, does not apply to: (1) The sources located in Bernalillo County, New Mexico; (2) the sources located on Indian lands as specified in the delegation agreement and in this notice; (3) the standards of performance for new residential wood heaters (subpart AAA) under 40 CFR part 60; and (4) the NESHAP radionuclide standards specified under 40 CFR part 61.

EFFECTIVE DATE: October 6, 1995.

ADDRESSES: The New Mexico Environment Department's request and delegation agreement may be obtained by writing to one of the following addresses:

Mr. Thomas H. Diggs, Chief, Air Planning Section (6PD–L), U.S. Environmental Protection Agency, 1445 Ross Avenue, suite 1200, Dallas, TX 75202, telephone: (214) 665–7214.

Ms. Cecilia Williams, Chief, Air Quality Bureau, New Mexico Environment Department (NMED), Harold Runnels Building, room So. 2100, 1190 St. Francis Drive, Santa Fe, NM 87502, telephone: (505) 827–0042.

FOR FURTHER INFORMATION CONTACT: Mr. Ken Boyce, Air Planning Section (6PD–L), U.S. Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202, telephone: (214) 665–7259.

SUPPLEMENTARY INFORMATION: The Clean Air Act Amendments (CAAA) of 1990 required the U. S. Environmental Protection Agency (EPA) to make significant changes to its approach to delegation of section 112 requirements. Prior to the 1990 Amendments to the CAA, delegation of section 112 requirements could occur without the need for a rulemaking by the EPA. However, new section 112(l) of the Act requires the EPA to approve, through rulemaking, a program for delegation which includes delegation of Federal requirements incorporated by reference. In an April 4, 1994, letter from Mr. Stan Meiburg, Director, Air, Pesticides & Toxics Division to Ms. Judith Espinosa, Secretary, New Mexico Environment Department, the EPA explained this procedural mechanism for delegation of section 112 requirements, and NMED's response, dated April 28, 1994, satisfactorily explained the State's course of action. Based on this correspondence, the Title V Federal Register notice (see 59 FR 59656–59660, November 18, 1994) outlined the State's plans to continue to incorporate by reference the Federal section 112 requirements regarding hazardous air pollutants into the New Mexico Air Quality Control Regulations, and stated that the NMED's request for approval of the part 70 program is also a request for approval of a program for delegation of unchanged section 112 standards. Based on approval of NMED's procedural mechanism for adopting Federal section 112 standards through incorporation by reference into the State's Part 70 Operating Permit Program, the EPA can continue to update the State's delegation of section 112 standards along with the update of section 111 NSPS. In the future, the effective date of the delegation for unchanged Federal standards under section 112 will be the effective date of the State's rule after its adoption. The effective date of the Federal delegation for NSPS under section 111 will continue to be, as has been the case in the past, the EPA's letter of approval of the State's request for the NSPS delegation update.

Sections 111(c) and 112(l)(1) of the Clean Air Act allow the Administrator of the EPA to delegate the EPA's authority to any State or local agency which can submit adequate regulatory procedures for implementation and enforcement of the NSPS and NESHAP programs. Authority for the NSPS and NESHAP programs were delegated to the State of New Mexico (except for sources located in Bernalillo County and on Indian lands) on March 15, 1985.

The State requested the EPA to update the delegation of authority to the State for the NSPS and the NESHAP programs from November 15, 1992, through February 1, 1995. The State's request includes a revision of Air Quality Control Regulations (AQCR) 20 NMAC 2.77 (NSPS) and 2.78 (NESHAP) as adopted by the New Mexico Environmental Improvement Board. AQCR's 20 NMAC 2.77 and 2.78 incorporate the Federal NSPS and NESHAP by reference through February 1, 1995.

The EPA reviewed the NMED requests, AQCR's and all other information submitted by the NMED, to support the delegation of these programs. The EPA has determined that the State has adequate authority and effective procedures for implementing and enforcing the NSPS and NESHAP programs. Therefore, the EPA is delegating full authority to the State from November 15, 1992, through February 1, 1995, for NSPS and for NESHAP, and authority for the technical and administrative review of new or amended NSPS and NESHAP promulgated by the EPA, subject to conditions and limitations of the original delegation agreement dated March 15, 1985. It is important to note that no delegation authority is granted to the NMED for Bernalillo County and Indian lands. Also, no authority is delegated to the State for 40 CFR part 60, subpart AAA, Standards of Performance for New Residential Wood Heaters, and for 40 CFR part 61 for the radionuclide NESHAP's. Specifically, the subparts for which delegation is excluded are subpart B (National Emission Standards for Radon–222 Emissions from Underground Uranium Mines), subpart H (National Emission Standards for Radionuclide Emissions from Department of Energy Facilities), subpart I (National Emission Standards for Radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities not covered by subpart H),

subpart K (National Emission Standards for Radionuclide Emissions from Elemental Phosphorus Plants), subpart Q (National Emission Standards for Radon Emissions from Department of Energy facilities), subpart R (National Emission Standards for Radon Emissions from Phosphogypsum Stacks), subpart T (National Emission Standards for Radon Emissions from the Disposal of Uranium Mill Tailings), and subpart W (National Emission Standards for Radon–222 Emissions from Licensed Uranium Mill Tailings).

Today's notice informs the public that the EPA is updating the delegation of full authority for the State to implement and enforce the NSPS and NESHAP promulgated by the EPA from November 15, 1992, through February 1, 1995. Authority for technical and administrative review is delegated for the new and amended standards after November 15, 1993. All of the information required pursuant to the Federal NSPS and NESHAP (40 CFR part 60 and 40 CFR part 61) should be submitted by sources located outside the boundaries of Bernalillo County and in areas outside of Indian lands, directly to the NMED, Harold Runnels Building, Room So. 2100, St. Francis Drive, Santa Fe, New Mexico 87502. Albuquerque/Bernalillo County is excluded from this action because this area is granted delegation authority under AQCR's 30 NSPS and 31 NESHAP to the City of Albuquerque's Environmental Health Department. Sources located on Indian lands in the State of New Mexico should submit required information to the EPA Region 6 office at the address given in this notice. All of the inquiries and requests concerning implementation and enforcement of the excluded standards under 40 CFR part 60, subpart AAA and 40 CFR part 61, subparts B, H, I, R, T, and W, in the State of New Mexico should be directed to the EPA Region 6 Office.

The Office of Management and Budget has exempted this information notice from requirements of section 6 of Executive Order 12866.

This delegation is issued under the authority of sections 111(c) and 112(l)(1) of the Clean Air Act, as amended (42 U.S.C. 7411(C) and 7412(D)).

List of Subjects

40 CFR Part 60

Air pollution control, Aluminum, Ammonium sulfate plants, Cement industry, Coal, Copper, Electric power plants, Fossil-Fuel steam generators, Glass and glass products, Grain, Iron, Lead, Metals, Motor vehicles, Nitric acid plants, Paper and paper industry, Petroleum phosphate, Fertilizer, Sewage disposal, Steel, Sulfuric acid plants, Waste treatment and disposal of zinc.

40 CFR Part 61

Air pollution control, Asbestos, Benzene, Beryllium, Hazardous materials, Mercury, Vinyl chloride.

Dated: September 21, 1995.

Russell Rhoades,

Acting Regional Administrator.

[FR Doc. 95–24876 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 70

[AD–FRL–5307–9]

Clean Air Act Final Interim Approval of Operating Permits Program; Monterey Bay Unified Air Pollution Control District, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final interim approval.

SUMMARY: The EPA is promulgating interim approval of the Operating Permits Program submitted by the Monterey Bay Unified Air Pollution Control District (Monterey or District) for the purpose of complying with federal requirements for an approvable state program to issue operating permits to all major stationary sources, and to certain other sources.

EFFECTIVE DATE: November 6, 1995.

ADDRESSES: Copies of Monterey's submittal and other supporting information used in developing the final interim approval are available for inspection (docket number CA–MN–95–1–OPS) during normal business hours at the following location: U.S. Environmental Protection Agency, Region IX, Air and Toxics Division, 75 Hawthorne Street, San Francisco, CA 94105.

FOR FURTHER INFORMATION CONTACT: Regina Spindler (telephone 415–744–1251), Mail Code A–5–2, U.S. Environmental Protection Agency, Region IX, Air and Toxics Division, 75 Hawthorne Street, San Francisco, CA 94105.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

Title V of the 1990 Clean Air Act Amendments (sections 501–507 of the Clean Air Act (''the Act'')), and implementing regulations at 40 Code of Federal Regulations (CFR) part 70 require that states develop and submit operating permits programs to EPA by November 15, 1993, and that EPA act to approve or disapprove each program within 1 year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the Act and the part 70 regulations, which together outline criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of Part 70, EPA may grant the program interim approval for a period of up to 2 years. If EPA has not fully approved a program by 2 years after the November 15, 1993 date, or by the end of an interim program, it must establish and implement a federal program.

On May 16, 1995, EPA proposed interim approval of the operating permits program for the Monterey Bay Unified Air Pollution Control District. See 60 FR 26013. The EPA received public comment on the proposal and is responding to those comments in this document and in a separate ''Response to Comments'' document contained in the docket at the Regional Office. As a result of public comment, EPA has modified one of the interim approval issues set forth in the May 16, 1995 proposal. The EPA's proposed action on the operating permits program is therefore being revised to reflect the modification of the interim approval issue. This change is discussed below in II.B. along with the other issues raised during the public comment period. The May 16, 1995 Federal Register notice also proposed approval of Monterey's interim mechanism for implementing section 112(g) and proposed approval under section 112(l) of the District's program for accepting delegation of section 112 standards as promulgated. The EPA did not receive any public comment on these proposed actions. With the exception of the modification to the interim approval issue discussed above, the proposed actions discussed above have not been altered as a result of public comment. In this notice EPA is taking final action to promulgate interim approval of the operating permits program and approving the section 112(g) mechanism and section 112(l) program for delegation noted above for Monterey.

II. Final Action and Implications

A. Analysis of District Submission

Monterey's original title V program was submitted by the California Air Resources Board (CARB) on December 6, 1993. Additional material was submitted on February 2, 1994 and April 7, 1994. The submittal was found to be complete on February 4, 1994. The EPA determined in its evaluation of Monterey's program that Rule 218, the

District's permitting regulation, contained several deficiencies that were cause for disapproval of the program. The EPA described these deficiencies and the corrections necessary to make the program eligible for interim approval in a letter from Felicia Marcus, EPA Region IX Administrator, to Abra Bennett, Monterey Air Pollution Control Officer (APCO), dated July 22, 1994. In response, Monterey adopted a revised regulation which was submitted by CARB on the District's behalf on October 13, 1994. On May 16, 1995, EPA proposed interim approval of Monterey's title V operating permits program in accordance with § 70.4(d), on the basis that the program ''substantially meets'' part 70 requirements. The analysis in the proposed document remains unchanged and will not be repeated in this final document. With the exception of the modification to the interim approval issue regarding affected state review discussed below in II.B.5., the program deficiencies identified in the proposed document, and outlined below in II.C., remain unchanged and must be corrected for the District to have a fully approvable program.

At the time of proposal, EPA believed that an implementation agreement would be completed prior to final interim approval. The EPA and Monterey have not yet finalized the implementation agreement, but are working to do so as soon as practicable.

B. Public Comments and Responses

The EPA received comments on the proposed interim approval of the Monterey program from one public commenter, the Monterey Bay Unified Air Pollution Control District. These comments are discussed below.

1. Insignificant Activities

Monterey commented that it would like to propose, for full title V program approval, emission levels for insignificant activities of 2 tons per year for criteria pollutants and the lesser of 1000 pounds per year, section 112(g) de minimis levels, or other title I significant modification levels for hazardous air pollutants and other toxics. The District commented that it believes these levels to be sufficiently below the applicability thresholds for all applicable requirements and will ensure that no unit potentially subject to an applicable requirement is left off of a title V permit application.

In the May 16, 1995 proposed interim approval of Monterey's program, EPA stated that it had proposed to accept, as sufficient for full approval of other state and district programs, the emission levels for insignificant activities as described above in Monterey's comment. The EPA stated that it believes these levels to be sufficiently below the applicability thresholds of many applicable requirements to assure that no unit potentially subject to an applicable requirement is left off a title V application. Monterey has commented that it believes these levels to be appropriate for determining insignificant activities in the District. If Monterey establishes these emission levels for defining insignificant activities in its program and submits this as a title V program revision to EPA, EPA will find that aspect of the insignificant activity definition fully approvable. As discussed below in II.C.7., to receive full approval of its insignificant activity provisions, Monterey must also revise Rule 218 to require that insignificant activities that are exempted because of size or production rate be listed in the permit application and to require that an application may not omit information needed to determine the applicability of, or to impose, any applicable requirement, or to evaluate the fee amount required.

2. ''Title I Modification''

Monterey commented that ''title I modifications'' should not be interpreted to include minor new source review and endorsed the recommendations and legal arguments made by CARB in its September 27, 1994 letter from Michael Scheible to the EPA Air Docket.

At the time of the May 16, 1995 proposed interim approval, EPA was in the process of determining the proper definition of title I modification, and therefore did not identify Monterey's treatment of title I modification as necessary grounds for either interim approval or disapproval. In an August 29, 1994 rulemaking proposal, EPA explained its view that the better reading of ''title I modifications'' includes minor NSR. However, the Agency solicited public comment on whether the phrase should be interpreted to mean literally any change at a source that would trigger permitting authority review under regulations approved or promulgated under title I of the Act. (59 FR 44572, 44573). This would include state preconstruction review programs approved by EPA as part of the State Implementation Plan under section 110(a)(2)(C) of the Clean Air Act.

The EPA has not yet taken final action on the August 29, 1994 proposal. However, in response to public comment on that proposal, the Agency has decided that the definition of ''title I modifications'' is best interpreted as not including changes reviewed under minor NSR programs. This decision was announced in a June 20, 1995 letter from Mary D. Nichols, EPA Assistant Administrator for Air and Radiation, to Congressman John D. Dingell, and will be included in a supplemental rulemaking proposal that will be published in September, 1995. Thus, EPA expects to confirm that Monterey's definition of ''title I modification'' is fully consistent with part 70.

The August 29, 1994 action proposed to, among other things, allow state programs with a more narrow definition of ''title I modifications'' to receive interim approval (59 FR 44572). The Agency stated that if, after considering the public comments, it continued to believe that the phrase ''title I modifications'' should be interpreted as including minor NSR changes, it would revise the interim approval criteria as needed to allow states with a narrower definition to be eligible for interim approval. If EPA does conclude, during this rulemaking, that Title I modifications should be read to include minor NSR, it will implement the interim approval option spelled out in the August 29, 1994 proposal.

3. Implementation Agreement

In the May 16, 1995 proposed interim approval, EPA stated that an implementation agreement is currently being developed by EPA and Monterey. Monterey commented that they disagree with EPA over the structure and the basis for an implementation agreement and take exception to the implementation agreement language contained in the notice and therefore suggest that it be removed prior to publication of the final notice. Since Monterey submitted this comment, EPA and the District have engaged in numerous conversations regarding the implementation agreement and Monterey has indicated that it does intend to develop an agreement with EPA. EPA and the District are currently negotiating the appropriate format and content of that agreement.

4. District Rule 201 Correction

Monterey commented that EPA had incorrectly stated in the May 16, 1995 proposal that Rule 201 ''was adopted or revised to implement title V.'' The District pointed out that Rule 201 was adopted prior to promulgation of part 70 and was not revised to implement title V. The EPA therefore revises the statement made in the May 16, 1995 proposal to state that Rule 201 was submitted as a supporting regulation of

the Monterey title V program. This change does not affect EPA's May 16, 1995 proposed action.

5. Affected State Review

In the May 16, 1995 proposed interim approval, EPA proposed that in order to receive full approval Monterey must revise Rule 218 to define and provide for giving notice to affected states per §§ 70.2 and 70.8(b). The EPA reasoned that although emissions from Monterey may not currently affect any neighboring states, Native American tribes may in the future apply for treatment as states for air program purposes and if granted such status would be entitled to affected state review under title V. (See EPA's proposed Tribal Air Rule at 59 FR 43956, August 25, 1994.) Monterey commented that it would be appropriate to revise Rule 218 to provide for giving notice to affected states at such time as a Native American tribe or tribes apply for treatment as a state. The EPA is concerned about the timing issues involved with delaying the adoption of affected state notice provisions in Monterey's program until tribes apply for state status. Although the federal rule that will enable tribes to apply for treatment as states has not yet been finalized, and there are no tribes currently eligible for treatment as a state under the Act, EPA believes that the likelihood of Native American tribes qualifying as affected states under part 70 is great and that Monterey will ultimately need to revise its rule to address this outcome. Nonetheless, EPA is willing to accept as an alternative to adopting affected state notice provisions up front, a commitment to: (1) Initiate rule revisions upon being notified by EPA of an application by an affected tribe for state status, and (2) provide affected state notice to tribes upon their filing for state status (i.e., prior to Monterey revising Rule 218 to incorporate affected state notice procedures).

C. Final Action

1. Monterey's Title V Operating Permits Program

The EPA is promulgating interim approval of the operating permits program submitted by the Monterey Bay Unified Air Pollution Control District. The District must make the following changes, or changes that have the same effect, to receive full approval:

(1) Revise section 1.3 to require that, regardless of the source's actual or potential emissions, acid rain sources and solid waste incineration units required to obtain a permit pursuant to section 129(e) of the Act may not be exempted from the requirement to obtain a permit pursuant to Rule 218. Section 70.3(b) requires that major sources, affected sources (acid rain sources), and solid waste incinerators may not be exempted from the program. Monterey's deferral for certain major sources other than acid rain sources and solid waste incinerators is allowable under EPA's ''Interim Approval Guidance,'' issued by John Seitz on August 2, 1993.

(2) Revise section 2.1.4 of the definition of ''Administrative Permit Amendments'' as follows:

''*requires more frequent* monitoring or reporting for the stationary source; or''

Increasing monitoring requirements could be a significant change to these requirements. Significant changes in monitoring must be processed as significant permit modifications. (§ 70.7(d)(1)(iii), § 70.7(e)(4))

(3) Revise the definition of ''Federally Enforceable Requirement'' in section 2.12 to include any standard or other requirement provided for in the State Implementation Plan approved or promulgated by EPA. This revision is necessary to make the section 2.12 definition consistent with the part 70 definition of ''Applicable requirement'' and with the Rule 218, section 4.2.4 requirement that each permit require compliance with any standard or requirement set forth in the applicable implementation plan.

(4) Revise section 2.18.4 of the definition of ''Minor Permit Modification'' to require that a minor permit modification may not *establish* or change a permit condition used to avoid a federally enforceable requirement to which the source would otherwise be subject. (§ 70.7(e)(2)(i)(A)(*4*))

(5) Revise section 3.1.6.12 to require that the compliance certification within the permit application include a statement indicating the source's compliance status with any applicable enhanced monitoring and compliance certification requirements of the Act. (§ 70.5(c)(9)(iv))

(6) Revise section 3.1.6.13 as follows to be consistent with § 70.5(c)(8)(iii)(C):

* * * a schedule of compliance approved by the District hearing board that identifies remedial measures, *including an enforceable sequence of actions,* with specific increments of progress, a final compliance date, testing and monitoring methods, recordkeeping requirements, and a schedule for submission of certified progress reports to the USEPA and the APCO at least every 6 months. *This schedule of compliance shall resemble and be at least as stringent as that contained in any judicial consent decree or administrative order to which the source is subject;* and * * *''

(7) Provide a demonstration that activities that are exempt from permitting under Rule 218 (pursuant to Rule 201, the District's permit exemption list) are truly insignificant and are not likely to be subject to an applicable requirement. Alternatively, Rule 218 may restrict the exemptions to activities that are not likely to be subject to an applicable requirement and emit less than District-established emission levels. The District should establish separate emission levels for HAP and for other regulated pollutants and demonstrate that these emission levels are insignificant compared to the level of emissions from and type of units that are required to be permitted or subject to applicable requirements. Revise Rule 218 to require that insignificant activities that are exempted because of size or production rate be listed in the permit application. Revise Rule 218 to require that an application may not omit information needed to determine the applicability of, or to impose, any applicable requirement, or to evaluate the fee amount required. (§ 70.5(c), § 70.4(b)(2))

(8) Revise section 3.5.3 to provide that the APCO shall also give public notice ''by other means if necessary to assure adequate notice to the affected public.'' (§ 70.7(h)(1))

(9) Revise Rule 218 to include the contents of the public notice as specified by § 70.7(h)(2).

(10) Revise Rule 218 to provide that the District shall keep a record of the commenters and of the issues raised during the public participation process so that the Administrator may fulfill her obligation to determine whether a citizen petition may be granted. (§ 70.7(h)(5))

(11) The EPA must be provided with 45 days to review the version of the permit that incorporates any public comments and that the District proposes to issue. Rule 218 indicates that the District intends to provide for concurrent public and EPA review of the draft permit. Therefore, the District must revise the rule to provide that EPA will have an additional 45 days to review the proposed permit if it is revised as a result of comments received from the public. (§ 70.8(a)(1))

(12) Revise Rule 218 to define and provide for giving notice to affected states per §§ 70.2 and 70.8(b). Alternatively, Monterey may make a commitment to: (1) Initiate rule revisions upon being notified by EPA of an application by an affected tribe for state status, and (2) provide affected

state notice to tribes upon their filing for state status (i.e., prior to Monterey's adopting affected state notice rules).

(13) Revise section 3.7.1 to require that the permit *shall* be reopened under the circumstances listed in sections 3.7.1.1 to 3.7.1.3. (§ 70.7(f)(1))

(14) Revise section 3.8.2 to provide, consistent with § 70.7(e)(2)(iv), that the District shall take action on a minor permit modification application within 90 days of receipt of the application or 15 days after the end of the 45-day EPA review period, whichever is later. Currently, the District rule provides that the permit be issued within 90 days after the application is deemed complete (section 3.3.2 provides 30 days from receipt for a completeness determination) or 60 days after written notice and concurrence from EPA, whichever is later. The EPA will not necessarily provide written notice and concurrence on minor permit modifications and the District rule does not address what action is taken should EPA not provide written notice. (§ 70.7(e)(2)(iv))

(15) Revise section 3.8.2 to provide that the action taken on a minor permit modification application in the timeframes discussed above in (14) shall be one of the following:

(a) Issue the permit modification as proposed;

(b) Deny the permit modification application;

(c) Determine that the requested modification does not meet the minor permit modification criteria and should be reviewed under the significant modification procedures; or

(d) Revise the draft permit modification and transmit to the Administrator the new proposed permit modification.

The current District rule states that the minor permit modification shall be completed within the timeframes discussed above in (14), but does not specify that the District must take one of the actions listed above. (§ 70.7(e)(2)(iv))

2. California Enabling Legislation—Legislative Source Category Limited Interim Approval Issue

Because California State law currently exempts agricultural production sources from permit requirements, the California Air Resources Board had requested source category-limited interim approval for all California districts. The May 16, 1995 proposed interim approval included a proposal to grant source category-limited interim approval to Monterey. The EPA is finalizing this source category-limited interim approval. In order for this program to receive full approval (and to avoid a disapproval upon the expiration of this interim approval), the California Legislature must revise the Health and Safety Code to eliminate the exemption of agricultural production sources from the requirement to obtain a permit.

The above described program and legislative deficiencies must be corrected before Monterey can receive full program approval.

The scope of Monterey's part 70 program approved in this notice applies to all part 70 sources (as defined in the approved program) within the District, except any sources of air pollution over which an Indian Tribe has jurisdiction. *See, e.g.,* 59 FR 55813, 55815–18 (Nov. 9, 1994). The term ''Indian Tribe'' is defined under the Act as ''any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village, which is federally recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.'' *See* section 302(r) of the CAA; *see also* 59 FR 43956, 43962 (Aug. 25, 1994); 58 FR 54364 (Oct. 21, 1993).

This interim approval, which may not be renewed, extends until November 6, 1997. During this interim approval period, Monterey is protected from sanctions, and EPA is not obligated to promulgate, administer and enforce a federal operating permits program in the District. Permits issued under a program with interim approval have full standing with respect to part 70, and the 1-year time period for submittal of permit applications by subject sources begins upon the effective date of this interim approval, as does the 3-year time period for processing the initial permit applications.

If Monterey fails to submit a complete corrective program for full approval by May 6, 1997, EPA will start an 18-month clock for mandatory sanctions. If Monterey then fails to submit a corrective program that EPA finds complete before the expiration of that 18-month period, EPA will be required to apply one of the sanctions in section 179(b) of the Act, which will remain in effect until EPA determines that the District has corrected the deficiency by submitting a complete corrective program. Moreover, if the Administrator finds a lack of good faith on the part of Monterey, both sanctions under section 179(b) will apply after the expiration of the 18-month period until the Administrator determined that the District had come into compliance. In any case, if, six months after application of the first sanction, the District still has not submitted a corrective program that EPA has found complete, a second sanction will be required.

If EPA disapproves Monterey's complete corrective program, EPA will be required to apply one of the section 179(b) sanctions on the date 18 months after the effective date of the disapproval, unless prior to that date the District has submitted a revised program and EPA has determined that it corrected the deficiencies that prompted the disapproval. Moreover, if the Administrator finds a lack of good faith on the part of the District, both sanctions under section 179(b) shall apply after the expiration of the 18-month period until the Administrator determines that Monterey has come into compliance. In all cases, if, six months after EPA applies the first sanction, Monterey has not submitted a revised program that EPA has determined corrects the deficiencies, a second sanction is required.

In addition, discretionary sanctions may be applied where warranted any time after the expiration of an interim approval period if Monterey has not timely submitted a complete corrective program or EPA has disapproved its submitted corrective program. Moreover, if EPA has not granted full approval to the District program by the expiration of this interim approval and that expiration occurs after November 15, 1995, EPA must promulgate, administer and enforce a federal permits program for Monterey upon interim approval expiration.

3. District Preconstruction Permit Program Implementing Section 112(g)

The EPA is approving the use of Monterey's preconstruction review program as a mechanism to implement section 112(g) during the transition period between promulgation of EPA's section 112(g) rule and adoption by Monterey of rules specifically designed to implement section 112(g). The EPA is limiting the duration of this approval to 12 months following promulgation by EPA of the section 112(g) rule.

4. Program for Delegation of Section 112 Standards as Promulgated

Requirements for approval, specified in 40 CFR 70.4(b), encompass section 112(l)(5) requirements for approval of a program for delegation of section 112 standards as promulgated by EPA as they apply to Part 70 sources. Section 112(l)(5) requires that the state's program contain adequate authorities, adequate resources for implementation, and an expeditious compliance schedule, which are also requirements under part 70. Therefore, EPA is also promulgating approval under section

112(l)(5) and 40 CFR 63.91 of the state's program for receiving delegation of section 112 standards that are unchanged from federal standards as promulgated. This program for delegations only applies to sources covered by the Part 70 program.

III. Administrative Requirements

A. Docket

Copies of the District's submittal and other information relied upon for the final interim approval, including one public comment letter received and reviewed by EPA on the proposal, are contained in docket number CA–MN–95–1–OPS maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this final interim approval. The docket is available for public inspection at the location listed under the **ADDRESSES** section of this document.

B. Executive Order 12866

The Office of Management and Budget has exempted this action from Executive Order 12866 review.

C. Regulatory Flexibility Act

The EPA's actions under section 502 of the Act do not create any new requirements, but simply address operating permits programs submitted to satisfy the requirements of 40 CFR part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

D. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that the approval action promulgated today does not include a federal mandate that may result in estimated costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This federal action approves pre-existing requirements under state or local law, and imposes no new federal requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: September 21, 1995.

John Wise,

Acting Regional Administrator.

Part 70, title 40 of the Code of Federal Regulations is amended as follows:

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, et seq.

2. Appendix A to part 70 is amended by adding paragraph (r) to the entry for California to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

The following district program was submitted by the California Air Resources Board on behalf of:

(r) *Monterey Bay Unified Air Pollution Control District:* submitted on December 6, 1993, supplemented on February 2, 1994 and April 7, 1994, and revised by the submittal made on October 13, 1994; interim approval effective on November 6, 1995; interim approval expires November 6, 1997.

* * * * *

[FR Doc. 95–24453 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 81

[NM–25–1–7119; FRL–5312–4]

Designation of Area for Air Quality Planning Purposes; New Mexico; Designation of Sunland Park Ozone Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Correction of final rule.

SUMMARY: The EPA published a final Federal Register (FR) action on June 12, 1995 (60 FR 30789–30791) which redesignated a portion of Dona Ana County, New Mexico (i.e. the Sunland Park area) from unclassifiable/attainment to nonattainment for the ozone National Ambient Air Quality Standards (NAAQS) with a marginal classification. The redesignation, based upon violations of the ozone NAAQS which were monitored from 1992–1994, became effective on July 12, 1995.

In the June 12, 1995, FR action, on page 30791 in the table entitled ''New Mexico—Ozone,'' the Classification Type should have read ''Marginal'' instead of ''Nonattainment.'' This FR action provides the correction.

EFFECTIVE DATE: October 6, 1995.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the addresses listed below. The interested persons wanting to examine these documents should make an appointment at least 24 hours before the visiting day:

U.S. Environmental Protection Agency, Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733.

New Mexico Environment Department, Air Monitoring & Control Strategy Bureau, 1190 St. Francis Drive, Room So. 2100, Santa Fe, New Mexico 87503.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth W. Boyce, Air Planning Section (6PD–L), U.S. EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7214.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: September 21, 1995.

William G. Laxton,

Acting Regional Administrator.

40 CFR part 81 is amended as follows:

PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. In section 81.332, the ozone table is amended by revising the entry ''AQCR 153 El Paso-Las Cruces-Alamogordo'' to read as follows:

§ 81.332 New Mexico.

* * * * *

NEW MEXICO—OZONE

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*
AQCR 153 El Paso-Las Cruces-Alamogordo:				
Dona Ana County (part)—The area bounded by the New Mexico-Texas State line on the east, the New Mexico-Mexico international line on the south, the Range 3E–Range 2E line on the west, and the N3200 latitude line on the north.	July 12, 1995 ..	Nonattainment	July 12, 1995 ..	Marginal
Remainder of Dona Ana County		Unclassifiable/Attainment.		
Lincoln County		Unclassifiable/Attainment.		
Otero County		Unclassifiable/Attainment.		
Sierra County		Unclassifiable/Attainment.		
* * *	*	*	*	*

[1] This date is November 15, 1990, unless otherwise noted.

[FR Doc. 95–24875 Filed 10–5–95; 8:45 am]
BILLING CODE 6560–50–P

40 CFR Part 258

[FRL–5312–9; F–95–AGDP–FFFFF]

RIN 2050–AE24

Delay of General Compliance Date for Small Municipal Solid Waste Landfills Located in Either Dry or Remote Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On August 10, 1995, the U.S. Environmental Protection Agency (EPA) published a proposed rule to provide to approved States and Tribes the flexibility to determine alternative ground-water monitoring requirements, on a site-specific basis, for small municipal solid waste landfills (MSWLFs) that are located in either dry or remote areas (hereafter referred to as ''qualifying small MSWLFs''). The proposed rule also solicited comments on a two-year delay, until October 9, 1997, of the general compliance date of the MSWLF criteria for qualifying small MSWLFs to allow EPA time to finalize the proposed alternatives. Today's rule finalizes only the delay of the compliance date.

EFFECTIVE DATE: The amendments in this final rule are effective October 2, 1995.

ADDRESSES: The public record for this rulemaking may be found in public docket number F–95–AGDP–FFFFF. All dockets are available for viewing in the RCRA Information Center (RIC), located in Room M2616, U.S. EPA, 401 M Street SW., Washington, DC 20460. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, except for Federal holidays. The public must make an appointment to view docket materials. Call 202–260–9327 for an appointment. Copies cost $0.15 per page for materials exceeding 100 pages.

FOR FURTHER INFORMATION CONTACT: For general questions on this rule, contact the RCRA/Superfund Hotline at 1–800–424–9346, TDD 1–800–553–7672 (hearing impaired); in the Washington, DC metropolitan area the number is 703–412–9810, TDD 703–412–3323. For technical questions, contact Mr. Andrew Teplitzky (703–308–7275) or Mr. Allen Geswein (Phone 703–308–7261): Office of Solid Waste, U.S. Environmental Protection Agency, Mail Code 5306W, 401 M St. SW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Authority
II. Background
A. 40 CFR Part 258 and Small Landfill Exemption
B. Summary of Proposed Rule on Alternative Ground-Water Monitoring and Delay of General Compliance Date
C. Details of Proposal to Delay the General Compliance Date
III. Response to Comments and Analysis of Issues Related to the Extension of the General Compliance Date for Qualifying Small MSWLFs
A. Comments Regarding the Two-Year General Compliance Date Extension
B. Comments Regarding the Two-Year Limited Extension
IV. Summary of This Rule
V. Consideration of Issues Related to Environmental Justice
VI. Impact Analysis
A. Executive Order 12866
B. Regulatory Flexibility Act
C. Paperwork Reduction Act
D. Executive Order 12875
E. Unfunded Mandates

I. Authority

The Agency is promulgating these regulations under the authority of Sections 1008(a)(3), 2002(a), 4004(a), and 4010(c) of the Resource Conservation and Recovery Act (RCRA), as amended, 42 U.S.C. 6907(a)(3), 6912(a), 6944(a), and 6949a(c).

II. Background

A. 40 CFR Part 258 and Small Landfill Exemption

When the Agency promulgated the solid waste disposal facility criteria final rule on October 9, 1991 (56 FR 50978), it included an exemption for owners and operators of certain small MSWLF units from the design and ground-water monitoring requirements of the criteria. To qualify for the exemption, the small landfill could only accept less than twenty tons of municipal solid waste per day (based on an annual average), have no evidence of existing ground-water contamination, and either: (1) serve a community that experiences an annual interruption of at least three consecutive months of surface transportation that prevents access to a regional waste management facility, or (2) be located in an area that annually receives less than or equal to 25 inches of precipitation and serve a community that has no practicable waste management alternative. In adopting this limited exemption, the Agency believed it had complied with the statutory requirement to protect human health and the environment, taking into account the practicable capabilities of small landfill owners and operators.

In January, 1992, the Sierra Club and the Natural Resources Defense Council (NRDC) filed a petition with the U.S. Court of Appeals, District of Columbia Circuit, for review of the Subtitle D criteria. On May 7, 1993, the Court of Appeals determined in *Sierra Club* v. *United States Environmental Protection*

Agency 992 F.2d 337 (D.C.Cir. 1993) that under RCRA section 4010(c), the only factor EPA could consider in determining whether facilities must monitor ground-water was whether such monitoring was ''necessary to detect contamination,'' not whether such monitoring is ''practicable.'' Thus, the Court vacated the small landfill exemption as it pertained to ground-water monitoring, and remanded that portion of the final rule to the Agency for further consideration.

Consequently, as part of the Agency's October 1, 1993 final rule delaying the effective date of the MSWLF criteria (58 FR 51536; October 1, 1993), EPA rescinded the exemption from ground-water monitoring for qualifying small MSWLFs. Also at that time, EPA delayed the effective date of the MSWLF criteria for qualifying small MSWLFs for two years (until October 9, 1995) to allow owners and operators of such small MSWLFs adequate time to decide whether to continue to operate in light of the Court's ruling, and to prepare financially for the added costs if they decided to continue to operate. This additional two-year period also was intended to provide time for EPA to determine if there are practical and affordable alternative ground-water monitoring systems or approaches that are adequate to detect contamination.

B. Summary of Proposed Rule on Alternative Ground-Water Monitoring and Delay of General Compliance Date

Since October 1993, the Agency has been collecting information and soliciting comment on cost-effective ground-water monitoring alternatives for small MSWLFs located in dry or remote locations. On August 10, 1995, EPA published a proposed rule (60 FR 40799) to provide to approved States and Tribes the flexibility to determine alternative ground-water monitoring requirements, on a site-specific basis, for qualifying small MSWLFs. Under this proposal, approved States and Tribes may consider site-specific alternatives to conventional ground-water monitoring that are relatively low in cost and will ensure ground-water contamination is detected in a timely manner. The August 10, 1995 proposed rule also requested comment on an extension of the general compliance date for qualifying small MSWLFs to allow time for the Agency to act on the proposed alternative standards.

The Agency established separate dockets and comment periods for the two aspects of this proposed rule. The docket number for the alternative ground-water monitoring requirements is F–95–AGAP–FFFFF and the comment period for this aspect of the August 10 proposal ends on November 8, 1995. The docket number for the extension is F–95–AGDP–FFFFF and the comment period for this aspect of the proposal ended on September 8, 1995. As noted in the August 10, 1995 proposed rule, the Agency established a shorter comment period for the extension to facilitate finalization of an extension by the time the current compliance date expires on October 9, 1995. Therefore, today's final rule pertains only to the extension of the compliance date; the Agency plans to publish a separate final rule pertaining to ground-water monitoring alternatives by October 1996.

C. Details of Proposal To Delay the General Compliance Date

In the August 10, 1995 proposed rule, the Agency requested comment on two approaches for extending the compliance date of the Part 258 criteria for qualifying small MSWLFs. The following discussion provides an overview of these two approaches.

1. Two-year Extension of the General Compliance Date

The first approach would provide a two-year extension of the general compliance date for qualifying small MSWLFs, from October 9, 1995 to October 9, 1997. Thus, qualifying small MSWLF units would not become subject to compliance with any of the Part 258 requirements until October 9, 1997 (one year after the alternative ground-water monitoring standards are expected to be finalized). At that time, these MSWLF units would be required to be in compliance with all applicable requirements of Part 258, including the ground-water monitoring (or alternative ground-water monitoring) requirements and financial assurance requirements. Should a qualifying small MSWLF unit cease receipt of waste prior to October 9, 1997, the owner/operator of that unit need only comply with the final cover requirements as specified in § 258.60(a). The final cover would have to be installed by October 9, 1998.

2. Limited Extension for Only Ground-water Monitoring and Financial Assurance

The second approach proposed in the August 10 proposed rule would maintain a general compliance date for qualifying small landfills of October 9, 1995, but would extend the effective date of ground-water monitoring and financial assurance until October 9, 1997. Under this alternative approach, an owner/operator that accepted waste after October 9, 1995 would have to comply with the location restrictions and operating requirements. Should that owner/operator cease receipt of waste by October 9, 1997 and place final cover on the landfill by October 9, 1998, that facility would be exempt from the ground-water monitoring requirements during the post-closure care period and from the financial assurance requirements for closure and post-closure care.

III. Response to Comments and Analysis of Issues Related to the Extension of the General Compliance Date for Qualifying Small MSWLFs

By the close of the public comment period, the Agency received 77 comments addressing the August 10 proposed extension of the compliance date. All of the comments received in response to this proposed rule were supportive of some type of an extension; i.e., either in favor of the general compliance date extension or the limited extension. None of the commenters suggested that qualifying small MSWLFs become subject to all of the requirements of 40 CFR Part 258 on October 9, 1995. Overall, 72 of the 77 comments were supportive of the two-year general compliance date extension, four commenters were supportive of the two-year limited extension, and one commenter did not take a position. The Agency also received and considered a number of comments after the close of the comment period; all of these comments were supportive of the two-year general compliance date delay. The following section summarizes and addresses the major public comments. A discussion of, and response to, the comments can be found in the docket for this rulemaking (95–AGDP–FFFFF).

A. Comments Regarding the Two-Year General Compliance Date Extension

Commenters expressing support for the general compliance date extension cited a number of reasons for their position. Many of the commenters in favor of the two-year general compliance date extension believed a full extension was necessary so that owners/operators of qualifying small MSWLFs could make economically and environmentally sound decisions regarding closure versus continued operation of their landfill after EPA has issued its final requirements for ground-water monitoring.

These commenters reaffirm, in part, the Agency's reasoning for an extension of the compliance date. As stated in the August 10 proposed rule, the Agency believes that qualifying small MSWLFs should be able to consider all site-specific flexibilities allowed under a

final rule on alternatives to ground-water monitoring in determining whether to remain in operation past the general compliance date of the regulation.

The majority of commenters also supported the two-year general compliance date extension because it would allow them to concentrate their efforts on a number of related activities: exploring alternative waste management options, completing arrangements for regional agreements, determining the feasibility of employing alternative ground-water monitoring technologies at their sites, and investigating the possibility of a successful no-migration demonstration under § 258.50(b) to become exempt from ground-water monitoring requirements. The Agency is aware, based on public comment, that many of these qualifying small MSWLF owners/operators simply do not have access to the resources and expertise to begin implementing the landfill criteria while also carrying out these other activities.

Based on the comments received, the Agency is encouraged by the commitment of qualifying small MSWLF owners/operators to either come into compliance with Part 258 or find alternative means of waste management. During this next two-year period, the Agency intends to issue final regulations governing alternative ground-water monitoring so that qualifying small MSWLF owners/operators may proceed with certainty. At the same time, during this extension period, the Agency strongly encourages qualifying small MSWLFs to complete their plans for safe management of their municipal solid waste.

A number of commenters from the State of Alaska, including the State Department of Environmental Conservation (DEC), submitted comments in favor of the two-year general compliance date extension. Alaska is important because the Agency estimates that nearly forty percent of all the qualifying small MSWLFs in the U.S., and virtually all of the MSWLFs considered ''remote,'' are located in the State of Alaska. These commenters provided a number of reasons why the extension is so important to qualifying small MSWLFs in Alaska.

First, Alaska is still in the process of acquiring MSWLF permit program approval. Until the State is approved, owners/operators of MSWLFs in Alaska are not able to take advantage of the flexibility available only to owners/operators in approved States and Tribes. For example, owners/operators may not use an alternative daily cover material unless that alternative is approved by the Director of an approved State/Tribe. If the operating requirements in the Part 258 criteria became effective (as in the case of the proposed limited extension), owners/operators in Alaska could not avail themselves of that flexibility. The State DEC contends that the two-year extension will allow the State time to complete the program approval process, thereby allowing communities, which generally have no other option but to operate their own landfills, to take advantage of the flexibility possible in approved States.

The Alaska State DEC described how location restrictions and land ownership problems in Alaska are complicating implementation of the MSWLF criteria for a number of communities who intend to upgrade their facilities. The State DEC contends that it is difficult to find land that is not in a flood plain, wetland, or adjacent to an airport, and, once a possible landfill location has been identified, land ownership becomes a problem. Because over 90 percent of the land in Alaska is owned by State or federal governments, with less than one-half of one percent in private ownership, and property transfer from public to private use is a long and cumbersome process, Alaska DEC contends that more time is needed for these communities to secure an alternative site. The DEC contends that requiring compliance at this time will force closure of many qualifying small MSWLFs, creating a significant environmental crisis in the State.

The Agency agrees with the Alaska commenters. Given this high concentration of qualifying small MSWLFs in the State, and considering the complicating factors unique to the State, the Agency believes these comments, as well as similar ones from the majority of other commenters, fully support and justify an extension of all of the Part 258 requirements. The Agency continues to be encouraged with the progress that the State is making towards completion of the permit program approval process and by the commitment on the part of the Alaskan villages in working towards safe solid waste disposal.

The Agency received several comments from Tribes in support of the two-year general compliance date extension. These commenters expressed many of the same concerns and views expressed by other commenters who are in favor of the two-year general compliance extension. In addition to these concerns, the Agency understands that many of the Tribes in the U.S. are located in the sparsely populated arid west in areas that are not conducive to regionalization and that many of these Tribes have not yet sought approval for a Tribal MSWLF permit program and therefore will not be able to take advantage of the flexibility in the Part 258 criteria that is available only to approved States and Tribes. Therefore, the Agency believes that many of these Tribes could use the additional time to consider applying for permit program approval or secure alternative waste management opportunities.

Finally, several commenters indicated that the two-year general compliance date extension would simply be easier for qualifying small MSWLF owners/operators to understand and implement than the alternative extension (i.e., an extension for ground-water monitoring and financial assurance only) discussed in the August 10, 1995 proposed rule. The Agency agrees with these commenters. In fact, while reviewing the public comments received in response to the proposed rule, the Agency found that a number of the commenters expressed some confusion with the two proposed extension options. The Agency does not believe that a simplified approach to an extension should stand alone as the sole reason for choosing the two-year general compliance date extension. However, in light of the potential confusion associated with the implementation of the alterative approach, together with all the other reasons cited in favor of the general extension, the Agency has decided to finalize the two-year extension of all provisions of Part 258 for qualifying small MSWLFs.

Four commenters expressed opposition to the two-year general compliance date extension. One commenter, a State environmental agency, expressed concern that a two-year general compliance date extension would encourage some of the communities that closed their landfills to join a regional facility to reopen their landfills and cancel their disposal contracts. The commenter indicated that this would disrupt the regional planning and capacity-building efforts already accomplished and could impair the ability of regional facilities to survive.

EPA is sympathetic to these concerns and recognizes that some qualifying small MSWLFs may opt to withdraw, perhaps temporarily, from a regional facility given today's two-year compliance date extension. However, the Agency did receive comments from two other State environmental agencies indicating that the reopening of landfills and subsequent withdrawal from regional contracts may not be a wide-spread phenomenon. One State environmental agency indicated that the regional commitments made by small

communities would not necessarily dissolve as a result of a two-year general compliance date extension. This State agency suggested that while the two-year general compliance date extension may delay certain regional projects, the extension would not eliminate the long-term finalization of such plans, if regionalization is in fact the appropriate choice in a certain area. This State agency, as well as a number of other commenters, added that the extra time will allow owners/operators to study their alternatives more fully and make better decisions.

A second State environmental agency commented that for landfills already closed, substantial effort would be required to reopen these facilities. This State also commented that communities that had previously been served by these closed landfills have already developed practical methods to dispose of their waste, therefore making it difficult for the MSWLF owner/operator to argue that the community has no practicable alternative to manage solid waste. The Agency agrees with this reasoning. To qualify for the small landfill exemption, the community must demonstrate that it has no practicable alternative to operating their own landfill. Many of the closed landfills have likely closed because they found it more practicable to join a regional facility than operate their own.

Based on many of the public comments received, the Agency generally is impressed by the progress that owners/operators of many qualifying small MSWLFs have made in their efforts to regionalize their waste management practices. The Agency encourages these facilities to continue honoring their regional commitments wherever practicable and does not believe that the two-year general compliance date extension will have a significant impact on efforts to develop regional arrangements. The Agency also wishes to remind owners/operators that have closed their MSWLFs and now wish to reopen to take advantage of today's two-year extension of the general compliance date must continue to demonstrate, pursuant to § 251.1(f)(2), that their landfill meets the criteria for the small landfill exemption described in § 258.1(f)(1).

Two commenters (one private MSWLF owner/operator and one State environmental agency) explained that a two-year general compliance date extension would be unfair to those landfills that have decided to remain open and expend the resources to comply with the MSWLF criteria. The Agency understands the position of these commenters. Furthermore, the Agency is encouraged by the private MSWLF owner's commitment to regulatory compliance. The Agency wishes to stress that today's extension does not imply that the Agency will eventually exempt qualifying small MSWLFs from the requirements of Part 258; it is simply a delay of the compliance date. At the time the new compliance date of October 9, 1997, becomes effective, all qualifying small MSWLFs will be required to comply with all applicable requirements of Part 258.

Two commenters discussed the environmental consequences of a general compliance date extension. One of the commenters argued that qualifying small MSWLFs should comply with a baseline level of environmental protection and proper operating practices that would be required under the limited extension. The other commenter, a State environmental agency, raised concerns that a two-year general extension could wipe out many years of progress made towards cleaning up small landfills that, in the past, have performed open burning and illegally disposed of ''dead animals, septage, liquids, and other 'unacceptable wastes.' ''

The Agency appreciates the concerns expressed by these two commenters. However, the Agency wishes to clarify that qualifying small MSWLFs that remain open during the two-year delay period should be in compliance with a number of location and operating requirements that have been federal standards since 1979 when the Criteria for Classification of Solid Waste Disposal Facilities and Practices were promulgated under 40 CFR Part 257. Such requirements include location restrictions related to floodplains and airports, as well as operational requirements regarding surface water discharges, disease vector control, daily cover, methane gas generation, access control, and open burning. Qualifying MSWLF owners/operators should continue to employ these proper operating practices at their facilities during the two-year general compliance date extension. Additionally, States and Tribes may choose to impose additional requirements as warranted and necessary to protect human health and the environment.

The Agency is concerned about the receipt of ''unacceptable'' wastes at qualifying small MSWLFs. The Agency notes that the acceptance of bulk, noncontainerized waste is restricted under the Part 258 regulations and owners/operators of qualifying small MSWLFs are encouraged to abide by this restriction during the two-year delay period. As discussed in the Agency's MSWLF criteria final rule preamble (56 FR 50978, October 9, 1991), restriction of noncontainerized bulk liquids should minimize the amount of leachate generation in the landfill. Additionally, qualifying small MSWLFs that accept regulated quantities of hazardous waste could become subject to the requirements of the hazardous waste regulations under Subtitle C of RCRA.

Finally, a State environmental agency commented that a two-year delay of the general compliance date will provide small communities with a false sense that the extension of the federal deadline provides an automatic extension to State deadlines where a State wishes to require earlier compliance dates. The Agency understands the concerns expressed by this commenter; however, the Agency wishes to clarify that today's rule is not intended to prevent States and Tribes from being more stringent than the federal regulations, including the establishment of earlier compliance dates.

B. Comments Regarding the Two-Year Limited Extension

The Agency received four comments in support of the alternative two-year limited extension for ground-water monitoring and financial assurance. These commenters generally declared their support for the two-year limited delay by expressing their concerns with the two-year general compliance date delay. These concerns have been noted and addressed in section III.A of today's preamble. Beyond their concerns with the two-year general delay, the four commenters did not provide major compelling arguments based solely on the merits of a two-year limited extension. A discussion of, and response to, these four comments can be found in the docket for this rulemaking (95–AGDP–FFFFF).

IV. Summary of This Rule

Today's final rule extends the general compliance date of the MSWLF criteria for two years, from October 9, 1995 to October 9, 1997, for qualifying small MSWLFs. This means that qualifying small MSWLFs are not subject to the requirements of 40 CFR Part 258 until October 9, 1997, so long as the MSWLF continues to qualify for the small landfill exemption in 40 CFR § 258.1(f)(1). Should a MSWLF no longer meet the conditions of § 258.1(f)(1), that landfill would become subject to all of the requirements of 40 CFR Part 258, including the design and ground-water monitoring requirements.

The Agency wishes to remind owners/operators of qualifying small MSWLFs that, until October 9, 1997, their MSWLFs are subject to the requirements of 40 CFR Part 257. Additionally, owners/operators of qualifying small MSWLFs may be subject to more stringent State/Tribal requirements; therefore, these owners/operators are encouraged to work with their respective State/Tribal programs to understand the requirements for their facilities.

As a result of today's final rule extending the general compliance date for two years for qualifying small MSWLFs, the Agency is making final conforming changes to appropriate portions of the regulatory language in 40 CFR Part 258. First, § 258.1(d)(3) and (e)(4) are revised to reflect the new compliance date of October 9, 1997. Second, the definition of ''New MSWLF unit'' under § 258.2 is modified to account for the new general compliance date of October 9, 1997. Third, the applicability section under Section 258.50(e) is revised by removing paragraphs (1) and (2), which allowed for two different effective dates for the ground-water monitoring requirements based on the distance of the MSWLF unit to a drinking water intake. Today's final rule creates one effective date (i.e., October 9, 1997) for ground-water monitoring for all qualifying small MSWLFs, regardless of their distance to a drinking water intake.

Finally, the Agency, wishes to clarify that with respect to qualifying small MSWLFs, today's final rule overrides a recent Agency final rule that extended the effective date of the financial assurance requirements, until April 9, 1997, for all MSWLFs subject to regulation under 40 CFR Part 258 (60 FR 17649, April 7, 1995). Today's rule delays the compliance date of the financial assurance requirements for qualifying small MSWLFs until October 9, 1997; the compliance date of the financial assurance requirements for all other MSWLFs continues to be April 9, 1997. Today's final rule amends the financial assurance regulatory language in § 258.70(b) and § 258.74(a)(5), (b)(1), (c)(1), and (d)(1) to clarify that the compliance date of the financial assurance requirements for qualifying small MSWLFs is October 9, 1997.

V. Consideration of Issues Related to Environmental Justice

EPA is committed to addressing environmental justice concerns and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, or income bears disproportionately high and adverse human health and environmental effects as a result of EPA's policies, programs, and activities, and all people live in clean and sustainable communities.

The Agency believes that today's rule extending the general compliance date for qualifying small MSWLFs will not have a disproportionately high and adverse environmental or economic impact on any minority or low-income group, or on any other type of affected community. The Agency believes that this rulemaking will enable some minority and/or low-income communities to continue to be served by a local landfill while they study their waste management alternatives in order to make an informed decision on how to provide safe management of municipal solid waste at the lowest possible cost to residents, including minority and low income residents.

VI. Impact Analysis

A. Executive Order 12866

Under Executive Order 12866, EPA must determine whether a regulatory action is significant and therefore subject to OMB review and the other provisions of the Executive Order. A significant regulatory action is defined by Executive Order 12866 as one that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or rights and obligations or recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

The Agency believes that this final rule does not meet the definition of a major regulation. Thus, the Agency is not conducting a Regulatory Impact Analysis, and today's final rule is not subject to review by the Office of Management and Budget (OMB) based upon Executive Order 12886.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) generally requires an agency to prepare, and make available for public comment, a regulatory flexibility analysis that describes the impact of a proposed or final rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have significant economic impact on a substantial number of small entities.

The effect of this final rule is to provide small entities with additional time to meet the requirements of Part 258. Therefore, pursuant to 5 U.S.C. 605b, the Agency believes that this final rule will not have a significant adverse impact on a substantial number of small entities.

C. Paperwork Reduction Act

The Agency has determined that there are no new reporting, notification, or recordkeeping provisions associated with today's final rule.

D. Executive Order 12875

Under Executive Order 12875, Federal agencies are charged with enhancing intergovernmental partnerships by allowing State and local governments the flexibility to design solutions to problems the citizenry is facing. Executive Order 12875 calls on Federal agencies to either pay the direct costs of complying with Federal mandates or to consult with representatives of State, local, or tribal governments prior to formal promulgation of the requirement. The Executive Order also relates to increasing flexibility for State, Tribal, and local governments through waivers. Today's final rule delaying the general compliance date of the MSWLF criteria does not impose unfunded federal mandates on State, Tribal, and local governments and is being undertaken to ensure that EPA is providing maximum flexibility to States, Tribes, and local governments. Additionally, the Agency has maintained dialog with States, Tribes, and local governments regarding ways of ensuring appropriate flexibility while maintaining protection of human health and the environment for small MSWLFs, particularly those in arid or remote locations. Therefore, the Agency believes that this consultation with States, Tribes, and local governments, in addition to the 30-day public comment period provided in the proposed rule, satisfies the requirement of this Executive Order.

E. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L 104–4, establishes requirements for federal

agencies to assess the effects of regulatory actions on state, local, and tribal governments, and the private sector. Under Section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, Section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objective of the rule. The provisions of Section 205 do not apply when they are inconsistent with applicable law. Moreover, Section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under Section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector.

List of Subjects in 40 CFR Part 258

Environmental protection, Reporting and recordkeeping requirements, Waste treatment and disposal

Dated: October 2, 1995.

Carol M. Browner,

Administrator.

For reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 258—CRITERIA FOR MUNICIPAL SOLID WASTE LANDFILLS

1. The authority citation for part 258 continues to read as follows:

Authority: 42 U.S.C. 6907(a)(3), 6912(a), 6944(a) and 6949a(c); 33 U.S.C. 1345 (d) and (e).

2. Section 258.1 is amended by revising paragraphs (d)(3) and (e)(4) to read as follows:

§ 258.1 Purpose, scope, and applicability.

* * * * *

(d) * * *

(3) MSWLF units that meet the conditions of paragraph (f)(1) of this section and receive waste after October 9, 1991 but stop receiving waste before October 9, 1997, are exempt from all the requirements of this part 258, except the final cover requirement specified in § 258.60(a). The final cover must be installed by October 9, 1998. Owners or operators of MSWLF units described in this paragraph that fail to complete cover installation by October 9, 1998 will be subject to all the requirements of this part 258, unless otherwise specified.

* * * * *

(e) * * *

(4) For a MSWLF unit that meets the conditions for the exemption in paragraph (f)(1) of this section, the compliance date for all applicable requirements of part 258, unless otherwise specified, is October 9, 1997.

* * * * *

3. Section 258.2 is amended by revising the definition of ''new MSWLF unit'' to read as follows:

§ 258.2 Definitions.

* * * * *

New MSWLF unit means any municipal solid waste landfill unit that has not received waste prior to October 9, 1993, or prior to October 9, 1997 if the MSWLF unit meets the conditions of § 258.1(f)(1).

* * * * *

4. Section 258.50 is amended by revising paragraph (e) to read as follows:

§ 258.50 Applicability.

* * * * *

(e) Owners and operators of all MSWLF units that meet the conditions of § 258.1(f)(1) must comply with all applicable ground-water monitoring requirements of this part by October 9, 1997.

* * * * *

5. Section 258.70 is amended by revising paragraph (b) to read as follows:

§ 258.70 Applicability and effective date.

* * * * *

(b) The requirements of this section are effective April 9, 1997 except for MSWLF units meeting the conditions of § 258.1(f)(1), in which case the effective date is October 9, 1997.

6. Section 258.74 is amended by revising paragraph (a)(5), the third sentence of paragraph (b)(1); the second sentence of paragraph (c)(1); and the second sentence of paragraph (d)(1) to read as follows:

§ 258.74 Allowable mechanisms.

* * * * *

(a) * * *

(5) The initial payment into the trust fund must be made before the initial receipt of waste or before the effective date of the requirements of this section (April 9, 1997, or October 9, 1997 for MSWLF units meeting the conditions of § 258.1(f)(1)), whichever is later, in the case of closure and post-closure care, or no later than 120 days after the corrective action remedy has been selected in accordance with the requirements of § 258.58.

* * * * *

(b) * * *

(1) * * * The bond must be effective before the initial receipt of waste or before the effective date of the requirements of this section (April 9, 1997, or October 9, 1997 for MSWLF units meeting the conditions of § 258.1(f)(1)), whichever is later, in the case of closure and post-closure care, or no later than 120 days after the corrective action remedy has been selected in accordance with the requirements of § 258.58. * * *

* * * * *

(c) * * *

(1) * * * The letter of credit must be effective before the initial receipt of waste or before the effective date of the requirements of this section (April 9, 1997, or October 9, 1997 for MSWLF units meeting the conditions of § 258.1(f)(1)), whichever is later, in the case of closure and post-closure care, or no later than 120 days after the corrective action remedy has been selected in accordance with the requirements of § 258.58. * * *

* * * * *

(d) * * *

(1) * * * The insurance must be effective before the initial receipt of waste or before the effective date of the requirements of this section (April 9, 1997, or October 9, 1997 for MSWLF units meeting the conditions of § 258.1(f)(1)), whichever is later, in the case of closure and post-closure care, or no later than 120 days after the corrective action remedy has been selected in accordance with the requirements of § 258.58. * * *

* * * * *

[FR Doc. 95–24871 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 282

[FRL–5295–1]

Underground Storage Tank Program: Approved State Program for Utah

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: The Resource Conservation and Recovery Act of 1976, as amended (RCRA), authorizes the U.S. Environmental Protection Agency (EPA) to grant approval to states to operate their underground storage tank programs in lieu of the federal program. 40 CFR part 282 codifies EPA's decision to approve state programs and incorporates by reference those provisions of the state statutes and regulations that will be subject to EPA's inspection and enforcement authorities under sections 9005 and 9006 of RCRA subtitle I and other applicable statutory and regulatory provisions. This rule codifies in part 282 the prior approval of Utah's underground storage tank program and incorporates by reference appropriate provisions of state statutes and regulations.

DATES: This regulation is effective December 5, 1995, unless EPA publishes a prior Federal Register notice withdrawing this immediate final rule. All comments on the codification of Utah's underground storage tank program must be received by the close of business November 6, 1995. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register, as of December 5, 1995, in accordance with 5 U.S.C. 552(a).

ADDRESSES: Comments may be mailed to Jo Taylor, 8HWM–WM, Hazardous Waste Management Division, Underground Storage Tank Program, U.S. EPA Region 8, 999–18th Street, Suite 500, Denver, Colorado, 80202–2466. Comments received by EPA may be inspected in U.S. EPA Region 8 Library, Suite 144, 999 18th Street, Denver, Colorado 80202–2466 from 12:00 p.m. to 4:00 p.m., Monday through Friday, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Jo Taylor, 8HWM–WM, Underground Storage Tank Program, U.S. EPA Region 8, 999–18th Street, Suite 500, Denver, Colorado, 80202–2466. Phone: (303) 293–1511.

SUPPLEMENTARY INFORMATION:

Background

Section 9004 of the Resource Conservation and Recovery Act of 1976, as amended, (RCRA), 42 U.S.C. 6991c, allows the U.S. Environmental Protection Agency (EPA) to approve state underground storage tank programs to operate in the state in lieu of the federal underground storage tank program. EPA published a Federal Register document announcing its decision to grant approval to Utah (60 FR 12709, March 8, 1995). Approval was effective on April 7, 1995.

EPA codifies its approval of State programs in 40 CFR part 282 and incorporates by reference therein the state statutes and regulations that will be subject to EPA's inspection and enforcement authorities under sections 9005 and 9006 of subtitle I of RCRA, 42 U.S.C. 6991d and 6991e, and other applicable statutory and regulatory provisions. Today's rulemaking codifies EPA's approval of the Utah underground storage tank program. This codification reflects the state program in effect at the time EPA granted Utah approval under section 9004(a), 42 U.S.C. 6991c(a) for its underground storage tank program. Notice and opportunity for comment were provided earlier on the Agency's decision to approve the Utah program, and EPA is not now reopening that decision nor requesting comment on it.

This effort provides clear notice to the public of the scope of the approved program in each state. By codifying the approved Utah program and by amending the Code of Federal Regulations whenever a new or different set of requirements is approved in Utah, the status of federally approved requirements of the Utah program will be readily discernible. Only those provisions of the Utah underground storage tank program for which approval has been granted by EPA will be incorporated by reference for enforcement purposes.

To codify EPA's approval of Utah's underground storage tank program, EPA has added section 282.94 to title 40 of the CFR. Section 282.94 incorporates by reference for enforcement purposes the State's statutes and regulations. Section 282.94 also references the Attorney General's Statement, Demonstration of Adequate Enforcement Procedures, the Program Description, and the Memorandum of Agreement, which are approved as part of the underground storage tank program under subtitle I of RCRA.

The Agency retains the authority under sections 9005 and 9006 of subtitle I of RCRA, 42 U.S.C. 6991d and 6991e, and other applicable statutory and regulatory provisions to undertake inspections and enforcement actions in approved states. With respect to such an enforcement action, the Agency will rely on federal sanctions, federal inspection authorities, and federal procedures, rather than the state authorized analogs to these provisions. Therefore, the approved Utah enforcement authorities will not be incorporated by reference. Section 282.94 lists those approved Utah authorities that would fall into this category.

The public also needs to be aware that some provisions of the State's underground storage tank program are not part of the federally approved state program. These non-approved provisions are not part of the RCRA subtitle I program because they are ''broader in scope'' than subtitle I of RCRA. See 40 CFR 281.12(a)(3)(ii). As a result, state provisions which are ''broader in scope'' than the federal program are not incorporated by reference for purposes of enforcement in part 282. Section 282.94 of the codification simply lists for reference and clarity the Utah statutory and regulatory provisions which are ''broader in scope'' than the federal program and which are not, therefore, part of the approved program being codified today. ''Broader in scope'' provisions cannot be enforced by EPA; the State, however, will continue to enforce such provisions.

Certification Under the Regulatory Flexibility Act

This rule codifies the decision already made (60 FR 12709, March 8, 1995) to approve the Utah underground storage tank program and thus has no separate effect. Therefore, this rule does not require a regulatory flexibility analysis. Thus, pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities.

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this rule from the requirements of Section 6 of Executive Order 12866.

Paperwork Reduction Act

Under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, federal agencies must consider the paperwork burden imposed by any information request contained in a proposed or final rule. This rule will not impose any information requirements upon the regulated community.

List of Subjects in 40 CFR Part 282

Environmental protection, Hazardous substances, Incorporation by reference, Intergovernmental relations, State program approval, Underground storage tanks, Water pollution control.

Dated: August 25, 1995.

Jack W. McGraw,

Acting Regional Administrator.

For the reasons set forth in the preamble, 40 CFR part 282 is proposed to be amended as follows:

PART 282—APPROVED UNDERGROUND STORAGE TANK PROGRAMS

1. The authority citation for part 282 continues to read as follows:

Authority: 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

2. Subpart B is amended by adding § 282.94 to read as follows:

Subpart B—Approved State Programs

§ 282.94 Utah State-Administered Program.

(a) The State of Utah is approved to administer and enforce an underground storage tank program in lieu of the federal program under Subtitle I of the Resource Conservation and Recovery Act of 1976 (RCRA), as amended, 42 U.S.C. 6991 *et seq.* The State's program, as administered by the Utah Department of Environmental Quality, was approved by EPA pursuant to 42 U.S.C. 6991c and part 281 of this Chapter. EPA approved the Utah program on March 8, 1995 and it was effective on April 7, 1995.

(b) Utah has primary responsibility for enforcing its underground storage tank program. However, EPA retains the authority to exercise its inspection and enforcement authorities under sections 9005 and 9006 of subtitle I of RCRA, 42 U.S.C. 6991d and 6991e, as well as under other statutory and regulatory provisions.

(c) To retain program approval, Utah must revise its approved program to adopt new changes to the federal subtitle I program which make it more stringent, in accordance with section 9004 of RCRA, 42 U.S.C. 6991c, and 40 CFR part 281, subpart E. If Utah obtains approval for the revised requirements pursuant to section 9004 of RCRA, 42 U.S.C. 6991c, the newly approved statutory and regulatory provisions will be added to this subpart and notice of any change will be published in the Federal Register.

(d) Utah has final approval for the following elements submitted to EPA in Utah's program application for final approval and approved by EPA on March 8, 1995. Copies may be obtained from the Underground Storage Tank Branch, Utah Department of Environmental Quality, 168 North 1950 West, 1st Floor, Salt Lake City, Utah 84116.

(1) *State statutes and regulations.* (i) The provisions cited in this paragraph are incorporated by reference as part of the underground storage tank program under subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(A) Utah Statutory Requirements Applicable to the Underground Storage Tank Program, 1995.

(B) Utah Regulatory Requirements Applicable to the Underground Storage Tank Program, 1995.

(ii) The following statutes and regulations are part of the approved state program, although not incorporated by reference herein for enforcement purposes.

(A) The statutory provisions include: Utah Code Unannotated (1994), Title 19, Chapter 6, Sections 19–6–112; 19–6–113; 19–6–115; 19–6–402(8), (11), and (23); 19–6–404(2)(f), (j), and (m); 19–6–405.5; 19–6–407(2) and (3); 19–6–410(3) as it pertains to penalties, (4)(b), and (5); 19–6–416; 19–6–418; 19–6–420(2), (4)(a), (5)(b), and (9)(b); 19–6–424.5; 19–6–425; 19–6–426(5) and (6); and 19–6–427.

(B) The regulatory provisions include: Administrative Rules of the State of Utah, Utah Administrative Code (1993), Sections R311–208–1; R311–208–2; R311–208–3; R311–208–4; R311–208–5; and R311–208–6.

(iii) The following statutory and regulatory provisions are broader in scope than the federal program, are not part of the approved program, and are not incorporated by reference herein for enforcement purposes.

(A) The statutory provisions include: Utah Code Unannotated (1994), Title 19, Chapter 6, Sections 19–6–402 (3), (4), (9), (14), (15), (20), and (26); 19–6–403(1)(a) (i) and (iv); 19–6–404(2)(c); 19–6–405.5; 19–6–408; 19–6–409; 19–6–410; 19–6–411; 19–6–412; 19–6–414; 19–6–415; 19–6–416; 19–6–417; 19–6–419; 19–6–420 (1), (3)(a), (3)(b), (5)(c), and (6); 19–6–421; 19–6–422; 19–6–423; 19–6–424; and 19–6–426 (1) through (4) and (7).

(B) The regulatory provisions include: Administrative Rules of the State of Utah, Utah Administrative Code (1993), Sections R311–200–1 (2), (5), (8), (10), (13), (20), (29), (42) through (49), (53), and (54); R311–201–2; R311–201–1; R311–201–3; R311–201–4; R311–201–5; R311–201–6; R311–201–7; R311–201–8; R311–201–9; R311–201–10; R311–201–11; R311–203–2; R311–206–2 (b) and (c); R311–206–4; R311–206–5 (b), (c), (d), and the words ''compliance or'' in (a); R311–206–6; R311–207–1; R311–207–2; R311–207–3; R311–207–4; R311–207–5; R311–207–6; R311–207–7; R311–207–8; R311–207–9; R311–209–1; R311–209–2; R311–209–3; and R311–209–4.

(2) *Statement of legal authority.* (i) ''Attorney General's Statement for Final Approval'', signed by the Attorney General of Utah on April 18, 1994, though not incorporated by reference, is referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(ii) Letter from the Attorney General of Utah to EPA, April 18, 1994, though not incorporated by reference, is referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(3) *Demonstration of procedures for adequate enforcement.* The ''Demonstration of Procedures for Adequate Enforcement'' submitted as part of the complete application in September 1993, though not incorporated by reference, is referenced as part of the approved underground storage tank program under subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(4) *Program Description.* The program description and any other material submitted as part of the original application in September 1993, though not incorporated by reference, are referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(5) *Memorandum of Agreement.* The Memorandum of Agreement between EPA Region VIII and the Utah Department of Environmental Quality, signed by the EPA Regional Administrator on March 1, 1995, though not incorporated by reference, is referenced as part of the approved underground storage tank program under subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

3. Appendix A to Part 282 is amended by adding in alphabetical order ''Utah'' and its listing.

Appendix A to Part 282—State Requirements Incorporated by Reference in Part 282 of the Code of Federal Regulations

* * * * *

Utah

(a) The statutory provisions include: Utah Code Unannotated (1994), Title 19, Chapter 6, Part 1, Solid and Hazardous Waste Act, and Chapter 6, Part 4, Underground Storage Tank Act:

Section 19–6–109 Inspections authorized.

Section 19–6–402 Definitions, except (3), (4), (8), (9), (11), (14), (15), (20), (23), and (26).
Section 19–6–402.5 Retroactive effect.
Section 19–6–403 Powers and duties of board, except (1)(a) (i) and (iv).
Section 19–6–404
Powers and duties of executive secretary, except (2)(c), (2)(f), (2)(j), and (2)(m).
Section 19–6–407 Underground storage tank registration—Change of ownership or operation—Civil penalty, except (2) and (3).
Section 19–6–413 Tank tightness test—Actions required after testing.
Section 19–6–420 Releases—Abatement actions—Corrective actions, except (1) through (3)(b), (4)(a), (5) (b) and (c), (6), and (9)(b).

(b) The regulatory provisions include:
(1) Administrative Rules of the State of Utah, Utah Administrative Code (1993):

Section R311–200–1 Definitions, except (2), (5), (8), (10), (13), (20), (29), (42) through (49), (53), and (54).
Section R311–202–1 Incorporation by Reference.
Section R311–203–1 Definitions.
Section R311–203–3 New Installations.
Section R311–203–4 Notification.
Section R311–204–1 Definitions
Section R311–204–2 Underground Storage Tank Closure Plan.
Section R311–204–3 Disposal.
Section R311–204–4 Subsequent Closure Notice.
Section R311–205–1 Definitions.
Section R311–205–2 Site Assessment Protocol.
Section R311–206–1 Definitions.
Section R311–206–2 Requirements for Issuance of Certificates, except (b) and (c).
Section R311–206–3 Application for Certificates.
Section R311–206–5 Revocation and Reissuance of Certificates, except (b), (c), (d), and the words ''compliance or'' in R311–206–5(a).

[FR Doc. 95–24873 Filed 10–5–95; 8:45 am]
BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 61

[CC Docket No. 94–1; FCC 95–394]

Price Cap Performance Review for Local Exchange Carriers; Treatment of Video Dialtone Services Under Price Cap Regulation

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On October 20, 1994, the Commission adopted a Memorandum Opinion and Order concluding that the basic video dialtone offerings of local exchange carriers (LECs) would be subject to the existing price cap rules. In that the order, the Commission stated it would initiate a rulemaking proceeding on whether to create a separate price cap basket for LEC video dialtone service. On February 7, 1995 the Commission issued a notice of proposed rulemaking in this docket seeking comment on whether to establish a separate price cap basket for LEC video dialtone service. The Report and Order adopted today establishes a separate price cap basket for video dialtone.

EFFECTIVE DATE: February 5, 1996.

FOR FURTHER INFORMATION CONTACT: Claudia Pabo, Policy and Program Planning Division, Common Carrier Bureau, (202) 418–1595 or Cheryl Lynn Schneider, Tariff Division, Common Carrier Bureau, (202) 418–1530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Report and Order adopted September 14, 1995 and released September 21, 1995. The full text of the Commission's decision is available for public inspection and copying during normal business hours in the FCC Public Reference Room (Room 230), 1919 M St., NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Suite 140, 2100 M Street, NW., Washington, DC 20037.

Regulatory Flexibility Analysis

We determined that section 605(b) of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), does not apply to the rule amendments adopted in this Order because they do not have a significant economic impact on a substantial number of small entities, as defined by section 301(3) of the Regulatory Flexibility Act. Carriers subject to price cap regulation for local exchange access services affected by the rule amendments adopted in this Order generally are large corporations or affiliates of such corporations.

Paperwork Reduction Analysis

Public burden for the collection of information is estimated to average 203 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and competing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing the burden, to the Federal Communications Commission, Records Management Branch, Paperwork Reduction Project (3060–0298), Washington, DC 20554 and to the Office of Management and Budget, Paperwork Reduction Project (3060–0298), Washington, DC 20503.

Summary of Report and Order

In this Order, the Commission adopts new rules regarding the price cap treatment of video dialtone common carrier service provided by local exchange carriers (LECs). The Order amends the Commission's rules to require that basic video dialtone offerings of price cap LECs must be included in a new, separate price cap basket. The video dialtone basket may not include any other ''broadband'' services. The Order also establishes an initial productivity or ''X-Factor'' for the video dialtone basket of zero.

The initial rates to be included in the video dialtone basket will be based upon the price cap new services test, as applied to video dialtone services. Consistent with this approach, the Commission will incorporate video dialtone rates into the new price cap basket in the first annual price cap tariff filing following the calendar year in which the new service is first offered, which may occur anywhere from six to eighteen months from the introduction of service. Moreover, as it has done with other price cap baskets, the Commission will assign an initial value of 100 to the PCI and the actual price index (API) for video dialtone service prior to adjustment for inflation and productivity, corresponding to the rates in effect just prior to the effective date of the annual filing in which rates for video dialtone service are included in the new basket.

The Commission decided not to divide the video dialtone basket into separate subcategories at this time. Video dialtone is a nascent service for which LECs have just begun to file tariffs, and the Commission expects that the LECs will employ a variety of architectures to deliver their offerings which could lead to varying rate structures for video dialtone services. Thus, it would be difficult to create a stable set of service categories within the new video dialtone basket at this time.

The Order imposes a lower banding limit on the video dialtone basket in addition to the protection provided by the new services test. Accordingly, LEC tariff filings reducing prices in excess of 15 percent per year relative to the PCI will not carry a presumption of lawfulness. Consistent with existing procedures, filings to implement rates below this level must be made on 45 days' notice, and be accompanied by a showing that the rates exceed average variable costs consistent with the cost

support requirements specified in § 61.49(d) of the Commission's rules.

The Commission also decided to exclude video dialtone costs and revenues from the calculation of a LEC's earnings from other regulated interstate services for purposes of sharing and the low-end adjustment once video dialtone costs are no longer *de minimis.* Under this plan, price cap LECs will be allowed to include video dialtone costs and revenues with those from other baskets for purposes of sharing and low-end adjustment calculations so long as their video dialtone costs are below a specified threshold. Once a LEC's costs rise above a *de minimis* level, however, the Commission will require the LEC to exclude video dialtone costs and revenues from its interstate rate of return calculations for sharing and the low-end adjustment.

Ordering Clause

Accordingly, it is ordered that, pursuant to authority contained in sections 4(i), 4(j), 201–205, 215, 218, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 201–205, 215, 218, 303(r), 403, and section 553 of Title 5, United States Code, part 61 of the Commission's rules, 47 CFR part 61, is amended as set forth below effective February 5, 1996.

List of Subjects in 47 CFR Part 61

Communications common carriers, Reporting and recordkeeping requirements.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

Rule changes

Part 61 of Title 47 of the CFR is amended as follows:

PART 61—TARIFFS

1. The authority citation for Part 61 continues to read as follows:

Authority: Secs. 4(i), 4(j), 201–205, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 201–205, 303(r), 403, unless otherwise noted.

2. Section 61.42 is amended by adding a new paragraph (d)(5) to read as follows:

§ 61.42 Price cap baskets and service categories.

* * * * *

(d) * * *

(5) To the extent that a local exchange carrier specified in §§ 61.41(a) (2) or (3) offers interstate video dialtone services, a basket for basic video dialtone services as described in § 63.54 of this chapter.

* * * * *

3. Section 61.45 is amended by revising paragraphs (b) introductory text and (h) and adding new paragraph (b)(3) to read follows:

§ 61.45 Adjustments to the PCI for Local Exchange Carriers.

* * * * *

(b) Adjustments to local exchange carrier PCIs for the baskets designated in §§ 61.42(d) (2), (3), (4), and (5), shall be made pursuant to the formula set forth in §§ 61.44 (b), and as further explained in §§ 61.44 (e), (f), (g), and (h).

* * * *

(3) Notwithstanding the value of X defined in § 61.44(b), the value of X applicable to the basket specified in § 61.42(d)(5) shall be 0%.

* * * * *

(h) To the extent a local exchange carrier elects the higher productivity factor, the election must be made in all baskets, except the video dialtone services basket, as designated in § 61.42(d)(5).

4. Section 61.47 is amended by adding a new paragraph (g)(6) to read as follows:

§ 61.47 Adjustments to the SBI; pricing bands.

* * * * *

(g) * * *

(6) Local exchange carriers subject to price cap regulation as that term is defined in § 61.3 shall use the methodology set forth in paragraphs (a) through (d) of this section to calculate a lower pricing band for the basket described in § 61.42(d)(5). The annual pricing flexibility for this basket, as reflected in the API, shall be limited to an annual decrease of fifteen percent, relative to the percentage change in the PCI for that basket, measured from the last day of the preceding tariff year.

* * * * *

6. Section 61.48 is amended by adding paragraph (j) to read as follows:

§ 61.48 Transition rules for price cap formula calculations.

* * * * *

(j) *Video Dialtone Services.* For local exchange carriers subject to price cap regulation, the video dialtone services basket, as designated in § 61.42(d)(5), shall be established with an initial PCI and API level of 100 in the first annual price cap tariff filing following competition of the base period in which the initial video dialtone service was introduced. The initial value of 100 for the PCI and API for video dialtone service prior to adjustment of inflation and productivity shall correspond to the rates in effect just prior to the effective date of the annual filing in which rates for video dialtone service are initially included in the video dialtone basket.

[FR Doc. 95–24884 Filed 10–5–95; 8:45 am]

BILLING CODE 6712–01–M

Proposed Rules

Federal Register
Vol. 60, No. 194
Friday, October 6, 1995

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 THE TREASURY

Customs Service

19 CFR Part 101

Customs Service Field Organization—Sioux Falls, SD

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations pertaining to the field organization of Customs by establishing Sioux Falls, South Dakota, as a port of entry. The change is being proposed as part of Customs continuing efforts to obtain more efficient use of its personnel, facilities, and resources and to provide better service to carriers, importers, and the general public.

DATES: Comments must be received on or before November 6, 1995.

ADDRESSES: Written comments (preferably in triplicate) may be addressed to the Regulations Branch, U.S. Customs Service, Franklin Court, 1301 Constitution Avenue, N.W., Washington, D.C. 20229. Comments submitted may be inspected at the Regulations Branch, Office of Regulations and Rulings, Franklin Court, 1099 14th Street, N.W., Suite 4000, Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Bob Jones, Office of Field Operations (202–927–0456).

SUPPLEMENTARY INFORMATION:

Background

As part of its continuing efforts to obtain more efficient use of its personnel, facilities, and resources and to provide better service to carriers, importers, and the general public, Customs is proposing to amend § 101.3 of the Customs Regulations (19 CFR 101.3) by establishing a port of entry at Sioux Falls, South Dakota, and encompassing the counties of Minnehaha and Lincoln in the State of South Dakota.

The Governor of the State of South Dakota has requested the establishment of a port of entry within South Dakota which does not presently have a port of entry. In support of the port of entry request, it has been stated to Customs that the proposed port of entry will yield significant immediate and future economic benefits for the State of South Dakota, including the retention and expansion of jobs, the more efficient transportation of imported and exported merchandise, the opportunity for establishment of a foreign trade zone, the expanded development of infrastructure within the proposed port, an enhanced business competitiveness for existing enterprises, and the opportunity to encourage new businesses to locate within South Dakota. The Customs office within the requested port of entry would be located at the Joe Foss Field airport in Sioux Falls which is the largest urban area within the State of South Dakota.

In T.D. 82–37 (47 FR 10137), as revised by T.D. 86–14 (51 FR 4559) and by T.D. 87–65 (52 FR 16328), Customs has set forth certain criteria which should be considered in connection with a request for port of entry designation. Specifically, the community for which such designation is requested must: (1) demonstrate that the benefits to be derived justify the Federal Government expense involved; (2) except in the case of land border ports, be serviced by at least two major modes of transportation (rail, air, water, or highway); and (3) except in the case of land border ports, have a minimum population of 300,000 within the immediate service area (approximately a 70-mile radius). In addition, T.D. 82–37, as revised, provides that at least one of the following actual or potential workload criteria must be met in the area to be serviced by the requested port of entry (minimum number of transactions per year): (1) 15,000 international air passengers; (2) 2,500 (formal) consumption entries, with the applicant location committing to optimal use of electronic data input means to permit integration with any Customs system for electronic processing of entries, and with no more than half of the 2,500 entries being attributed to one private party; (3) for land border ports, 150,000 vehicles; (4) 2,000 scheduled international aircraft arrivals (passengers and/or cargo); (5) 350 cargo vessel arrivals; or (6) any appropriate combination of the foregoing. Finally, T.D. 82–37, as revised, provides that facilities at the location must include wharfage and anchorage adequate for oceangoing vessels in the case of a water port, cargo and passenger facilities, warehousing space for the secure storage of imported cargo pending final Customs inspection and release, and administrative office space, inspection areas, storage areas, and other space necessary for regular Customs operations.

In connection with the request for designation of the Sioux Falls port of entry it has been represented to Customs that the cost to the Federal Government would only involve the services of one full-time Customs official and therefore would be minimal when compared to the significant benefits, described above, that port of entry status would impart to the South Dakota business community. As regards transportation services, Sioux Falls is located at the junction of two major interstate highways (Interstate 90 and Interstate 29), is serviced by a major national freight railway company, and is serviced at the Joe Foss Field airport by national passenger and cargo airlines, express air freight services and commuter airlines. It has also been represented to Customs that the greater metropolitan area of Sioux Falls has a population of 139,236 based on 1990 census figures and that a population of well over 300,000 exists within a 70-mile radius of Sioux Falls. With regard to actual or potential workload, the only figures provided to Customs concerned annual projections of import entries that would be filed within the requested port of entry by existing businesses, with no single company accounting for more than half of the projected entries: 2,709 in 1996, 3,147 in 1997, and 3,253 in 1998; it was also stated to Customs that the Sioux Falls Regional Airport Authority is committed to making optimal use of electronic data transfer capability to permit integration with the Customs Automated Commercial System for processing entries. Finally, it has been represented to Customs that the Joe Foss Field airport has exceptional cargo and passenger facilities, that passenger areas can be secured to accommodate international arrival passenger clearance, that there are several warehouse facilities in close proximity

to the Joe Foss Field airport that are suitable for the secure storage of cargo pending inspection and release by Customs, and that the Sioux Falls Regional Airport Authority has committed to providing administrative office space, inspection areas, storage areas, and other space necessary for regular Customs operations and will also furnish the Customs office with necessary communications equipment such as a computer, a telephone, a facsimile machine, and computer lines as well as access to photocopiers.

Based on the information provided to Customs and summarized above, Sioux Falls would meet the current minimum criteria for port of entry designation set forth in T.D. 82–37, as revised. It is noted that the proposal relies on potential, rather than actual, workload figures. Therefore, even if the proposed port of entry designation is adopted as a final rule, Customs will in 3 years review the actual workload generated within the port of entry. If that review indicates that the actual workload is below the T.D. 82–37 standards, procedures will be instituted to revoke port of entry status. Of course, if port of entry status is revoked, the City of Sioux Falls will have the opportunity to apply for user fee airport status under 19 U.S.C. 58b.

Proposed Limits of Port of Entry

The geographical limits of the proposed port of entry of Sioux Falls would be as follows:

All of Minnehaha and Lincoln Counties in the State of South Dakota.

If the proposed port of entry designation is adopted, the list of Customs ports of entry in 19 CFR 101.3(b) will be amended accordingly.

Comments

Before adopting this proposal, consideration will be given to any written comments (preferably in triplicate) timely submitted to Customs. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, Franklin Court, 1099 14th Street, N.W., Suite 4000, Washington, D.C.

Authority

This change is proposed under the authority of 5 U.S.C. 301 and 19 U.S.C. 2, 66 and 1624.

The Regulatory Flexibility Act and Executive Order 12866

Customs routinely establishes, expands, and consolidates Customs ports of entry throughout the United States to accommodate the volume of Customs-related activity in various parts of the country. Although this document is being issued with notice for public comment, it is not subject to the notice and public procedure requirements of 5 U.S.C. 553 because it relates to agency management and organization. Accordingly, this document is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). In addition, matters involving agency management and organization are not subject to Executive Order 12866.

Michael H. Lane,

Acting Commissioner of Customs.

Approved: September 14, 1995.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 95–24864 Filed 10–5–95; 8:45 am]

BILLING CODE 4820–02–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[LA 32–1–7190; FRL–5309–8]

Approval and Promulgation of Implementation Plans; Louisiana

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve Louisiana's request to grant an exemption for the Baton Rouge ozone nonattainment area from the applicable oxides of nitrogen (NO_X) transportation conformity requirements. On July 25, 1995, Louisiana submitted, to the EPA, a State Implementation Plan (SIP) revision request for an exemption (under section 182(b)(1) of the Clean Air Act (Act)) from the conformity requirements for NO_X for the Baton Rouge ozone nonattainment area, which is classified as serious. The State of Louisiana bases its request for Baton Rouge upon a modeling demonstration that additional NO_X reductions would not contribute to ozone attainment in the nonattainment area.

DATES: Comments on this proposed action must be received in writing on or before November 6, 1995.

ADDRESSES: Written comments on this action should be addressed to Mr. Thomas Diggs, Chief, Air Planning Section, at the EPA Regional Office listed below. Copies of the documents relevant to this proposed action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

U.S. Environmental Protection Agency, Region 6, Multimedia Planning and Permitting Division, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733.

Louisiana Department of Environmental Quality, H.B. Garlock Building, 7290 Bluebonnet, Baton Rouge, Louisiana 70810.

FOR FURTHER INFORMATION CONTACT: Ms. Jeanne McDaniels or Mr. Quang Nguyen, Air Planning Section (6PD-L), Multimedia Planning and Permitting Division, U.S. EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7214.

SUPPLEMENTARY INFORMATION:

Background

Clean Air Act section 176(c)(3)(A)(iii) requires, in order to demonstrate conformity with the applicable SIP, that transportation plans and transportation improvement programs (TIPs) contribute to emissions reductions in ozone and carbon monoxide nonattainment areas during the period before control strategy SIPs are approved by the EPA. This requirement is implemented in 40 CFR 51.436 through 51.440 (and 93.122 through 93.124), which establishes the so-called ''build/no-build test.'' This test requires a demonstration that the ''Action'' scenario (representing the implementation of the proposed transportation plan/TIP) will result in lower motor vehicle emissions than the ''Baseline'' scenario (representing the implementation of the current transportation plan/TIP). In addition, the ''Action'' scenario must result in emissions lower than 1990 levels.

The November 24, 1993, final transportation conformity rule does not require the build/no-build and less-than-1990 tests for NO_X as an ozone precursor in ozone nonattainment areas where the Administrator determines that additional reductions of NO_X would not contribute to attainment of the National Ambient Air Quality Standard (NAAQS) for ozone. Clean Air Act section 176(c)(3)(A)(iii), which is the conformity provision requiring contributions to emissions reductions before SIPs with emissions budgets can

be approved, specifically references Clean Air Act section 182(b)(1). That section requires submission of State plans that, among other things, provide for specific annual reductions of volatile organic compounds (VOCs) and NO_X emissions ''as necessary'' to attain the ozone standard by the applicable attainment date. Section 182(b)(1) further states that its requirements do not apply in the case of NO_X for those ozone nonattainment areas for which the EPA determines that additional reductions of NO_X would not contribute to ozone attainment.

For ozone nonattainment areas, the process for submitting waiver requests and the criteria used to evaluate them are explained in the December 1993 EPA document ''Guidelines for Determining the Applicability of Nitrogen Oxides Requirements Under Section 182(f),'' and the May 27, 1994, and February 8, 1995, memoranda from John Seitz, Director of the Office of Air Quality Planning and Standards, to Regional Air Directors, titled ''Section 182(f) NO_X Exemptions—Revised Process and Criteria.''

In a petition dated November 17, 1994, and in two follow-up letters to the petition, the Louisiana Department of Environmental Quality (LDEQ) requested that the EPA grant an exemption from the requirements of section 182(f) of the Act to include the reasonably available control technology (RACT) and new source review (NSR) requirements for major stationary sources of NO_X, inspection and maintenance (I/M) NO_X requirements, and transportation and general conformity requirements for NO_X.

On August 18, 1995, the EPA published a rulemaking proposing approval of the NO_X exemption for the RACT, NSR, I/M, and general conformity requirements. The Region did not propose approval of the transportation conformity exemption in that notice, however. The reason for not including the transportation conformity among the proposed exemptions stems from an April 1995 agreement by the EPA to change the procedural mechanism through which a NO_X exemption from transportation conformity exemption would be granted (*EDF et al. v. U.S. E.P.A*, No. 94–1044, U.S. Court of Appeals, D.C. Circuit). (The EDF et al. argued that NO_X exemptions are provided for in two separate parts of the Act in sections 182(b)(1) and 182(f), but that the Act's transportation conformity provisions in section 176(c)(3) explicitly reference section 182(b)(1).) Therefore, instead of a petition under section 182(f), transportation conformity NO_X exemptions for ozone nonattainment areas that are subject to section 182(b)(1) now need to be submitted as a SIP revision. The Baton Rouge ozone nonattainment area is classified as serious and, thus, is subject to section 182(b)(1).

The transportation conformity requirements are found at sections 176(c) (2), (3), and (4). The conformity requirements apply on an areawide basis in all nonattainment and maintenance areas. As originally promulgated, the EPA's transportation conformity rule [1] and general conformity rule [2] referenced the section 182(f) exemption process as a means for exempting any nonattainment area from NO_X conformity requirements. On August 29, 1995, the EPA amended the transportation conformity rule to instead reference section 182(b)(1) as the means for exempting areas subject to section 182(b)(1) from the transportation conformity NO_X requirements.[3]

The July 25, 1995, SIP revision request from Louisiana has been submitted to meet the requirements of a formal SIP revision submittal in accordance with the 182(b)(1) requirements. A public hearing on this SIP revision request was held on June 29, 1995. The Baton Rouge serious ozone nonattainment area consists of the following parishes: East Baton Rouge, West Baton Rouge, Pointe Coupee, Livingston, Iberville, and Ascension.

Section 182(b)(1) requires submittal of a plan revision that provides for reasonable further progress (RFP) reductions for moderate and above ozone nonattainment areas. The plan must provide for specific annual reductions in emissions from VOCs and NO_X, as necessary to attain the national primary ambient air quality standard for ozone by the attainment date applicable under the Act. Further, the requirement shall not apply in the case of NO_X for which the Administrator determines that additional reductions of NO_X would not contribute to attainment. In evaluating the 182(b) SIP revision request, the EPA considered whether additional NO_X reductions would contribute to attainment of the standard in the Baton Rouge area.

As outlined in the relevant EPA guidance, the use of photochemical grid modeling is the recommended approach for testing contribution of NO_X emission reductions to attainment of the ozone standard. This approach simulates conditions over the modeling domain that may be expected at the attainment deadline for three emission reduction scenarios: (1) Substantial VOC reductions, (2) substantial NO_X reductions, and (3) both VOC and NO_X reductions. If the areawide predicted maximum one-hour ozone concentration for each day modeled under scenario (1) is less than or equal to those from scenarios (2) and (3) for the corresponding days, the test is passed and the section 182(f) NO_X emissions reduction requirements would not apply.

The EPA has made a determination under section 182(b)(1) that the NO_X requirements do not apply. The EPA has based its decision on an urban airshed modeling (UAM) demonstration that additional NO_X reductions would not contribute to attainment in the Baton Rouge area.

State Submittal

On July 25, 1995, the State of Louisiana submitted, as a revision to the SIP, a request for an exemption from the transportation conformity NO_X requirements. The State bases its request on an urban airshed modeling (UAM) demonstration that additional NO_X reductions would not contribute to attainment in the area. The modeling demonstrates, consistent with the EPA's December 1993 section 182(f) guidance, that decreases in ozone concentrations resulting from VOC reductions alone are equal to or greater than decreases obtained from NO_X reductions or a combination of VOC and NO_X reductions. The State's submission includes a letter dated July 17, 1995, from the Governor of Louisiana requesting the exemption to the NO_X transportation conformity requirements and a summary of the UAM modeling results. The State of Louisiana also provided supplemental technical reports based on the modeling demonstration in the Baton Rouge post-1996 rate-of-progress (ROP) plan submitted to the EPA on November 15, 1994, pursuant to the requirements of section 182(c)(2)(B) of the Act. These reports contained the following: base case model inputs, base case performance evaluation, 1999 emissions report, and attainment modeling report. These additional technical reports provided supplemental detail and

[1] ''Criteria and Procedures for Determining Conformity to State or Federal Implementation Plans of Transportation Plans, Programs, and Projects Funded or Approved under Title 23 U.S.C. of the Federal Transit Act,'' November 24, 1993 (58 FR 62188).

[2] ''Determining Conformity of General Federal Actions to State or Federal Implementation Plans; Final Rule,'' November 30, 1993 (58 FR 63214).

[3] ''Transportation Conformity Rule Amendments: Authority for Transportation Conformity Nitrogen Oxides Waivers; Interim Final Rule,'' August 29, 1995 (60 FR 44762).

documentation on the modeling information provided to the EPA in the State's petition.

Analysis of State Submission

In evaluating the section 182(b)(1) transportation conformity NO_X exemption, the EPA applied the same criteria/guidance used for evaluating section 182(f) NO_X waiver requests. The following items are the basis for the EPA's action proposing to approve the State of Louisiana's section 182(b)(1) NO_X exemption request for the Baton Rouge ozone nonattainment area. Please refer to the EPA's Technical Support Document and the State's submittal for more detailed information.

A. Consistency With EPA NO_X Exemption Guidance

Chapter 4 of the EPA's December 1993 section 182(f) guidance requires that photochemical grid modeling be used to simulate conditions resulting from three emission reduction scenarios: (1) Substantial VOC reductions; (2) Substantial NO_X reductions; and (3) both VOC and NO_X reductions. To demonstrate that NO_X reductions would not contribute to attainment, the areawide predicted maximum 1-hour ozone concentration for each day modeled under scenario (1) must be less than or equal to that from scenarios (2) and (3) for the same day. Chapter 7 specifies that the application of UAM should be consistent with the techniques specified in the EPA ''Guideline on Air Quality Models (Revised),'' and ''Guideline for Regulator Application of the UAM (July 1991).'' In addition, Chapter 8 of the EPA's December 1993 section 182(f) guidance requires that the modeling simulating conditions from the NO_X emission reduction scenarios include NO_X emission increases after November 15, 1992, due to new or modified stationary sources of NO_X. (Many of these sources would be subject to the best available control technology requirement through the prevention of significant deterioration program, but not to NSR offsets.) As discussed in the next section, the State has met these requirements by using the UAM consistent with the EPA's guidance.

B. UAM Modeling Analysis

The LDEQ used UAM version IV, an EPA-approved photochemical grid model, to develop the attainment demonstration for the Baton Rouge area. The State's modeling activities were performed as outlined in the UAM modeling protocols, according to the EPA's ''Guideline for Regulatory Application of the Urban Airshed Model.'' A specific modeling protocol was developed by the State for its modeling activities. The State's modeling protocol was reviewed and approved by the EPA. The discussion below summarizes the EPA's analysis of how the State's modeling demonstrations complied with the EPA's guidance. Please refer to the EPA's Technical Support Document for more detailed information.

1. Episode Selection

The State used the EPA ''Guideline For Regulatory Application of The Urban Airshed Model'' to select episodes for use in the Baton Rouge UAM modeling exercises. Data from 1987 through 1991 were examined for episodes which cover at least 48 consecutive hours and the worst-case meteorological conditions. Three episodes were selected for the UAM analysis for the area.

2. Model Domain and Meteorological Input

The LDEQ used a sufficiently large modeling domain for Baton Rouge to ensure that the model captures the movement of ozone episodes as a result of the VOC and NO_X emissions emitted from the surface sources. Meteorological data were collected from numerous monitoring stations in the area. The LDEQ followed the methods described in the UAM user's guides to develop model inputs for wind field data, mixing heights, temperature, and meteorological scalars for the areas.

3. Emissions Inventory

The Baton Rouge modeling exercises were conducted using VOC and NO_X emission inventories compiled by survey and direct measurement by the LDEQ. The modeling emissions inventories are composed of point source, area, on-road mobile, off-road mobile, and biogenic emissions. Where applicable, emissions were adjusted for pertinent conditions related to the episode day to be modeled, thus producing day-specific emissions. The State followed the EPA's procedures for developing episode-specific emission inventories.

The EPA's section 182(f) guidance explains that, in general, the purpose of the section 182(f) requirements for NO_X is related to attainment of the ozone standard, which suggests that an analysis be focussed on the time that attainment of that standard is required. For the purpose of a section 182(f) modeling demonstration, this means that the projected emissions inventory for the attainment year should be used.

For Baton Rouge, the 1999 attainment year modeling inventory was developed from the 1990 base year emission inventory and adjusted to reflect the projected conditions for the attainment year. Demographic and econometric forecasting methods were employed to project activities levels to 1999, which, in turn, were used to develop a projected emissions inventory for 1999. The State then applied the VOC emission reductions that are projected to be realized through 1996 from the control regulations contained in the Baton Rouge 15 percent ROP SIP submitted to the EPA on November 15, 1994, and the NO_X controls implemented between 1990 and 1994 due to facilities' voluntary participation in the early NO_X reduction program. (The 1999 inventories did not incorporate any additional NO_X emission reductions that would have been achieved through implementation of the NO_X RACT, NSR, general and transportation conformity, or NO_X-related I/M provisions.)

4. Model Performance

For Baton Rouge, both graphical and statistical performance measures were used to evaluate the model. Using these analyses, the predicted results from the model were compared to the observed results for each episode. These analyses indicated that, overall, the model performed satisfactorily for the three episodes used for the UAM demonstration.

5. Modeling Demonstration

The EPA's section 182(f) guidance requires the State to model three emission reduction scenarios to evaluate the benefits of NO_X reductions: (1) Substantial VOC reductions; (2) substantial NO_X reductions; and (3) both VOC and NO_X reductions. For the section 182(b)(1) exemption, the LDEQ modeled the three emission reduction scenarios for all three episodes using the 1999 projected emission inventory, which includes the voluntary early (1990–1994) point source NO_X reductions and the VOC emission controls to be implemented through 1996 (i.e., 15 percent ROP). The LDEQ modeled the scenarios using across-the-board reductions in the projected VOC and NO_X point source emission inventories. The State first modeled substantial NO_X and VOC emission reductions as follows: A 100 percent reduction in point source VOC emissions alone; a 100 percent reduction in point source NO_X emissions alone; and a 100 percent reduction in both VOC and NO_X emissions combined. This reduction

represents approximately 46 percent of the total projected anthropogenic VOC emissions and approximately 57% of the total projected NO_X emissions. The State also modeled smaller across-the-board reductions in the projected VOC and NO_X point source emissions of 25%, 50%, and 75% separately and then combined in order to more accurately characterize near-term VOC and NO_X control scenarios.

As explained in the EPA's section 182(f) guidance, the EPA believes it is appropriate to focus this analysis on the areawide maximum 1-hour predicted ozone concentration, since this value is critical for the attainment demonstration. For all three episodes, the controlling day showed that the domain-wide predicted maximum ozone concentrations are lowest when only VOC reductions are modeled. In contrast, further NO_X reductions increase the domain-wide maximum ozone concentrations. Please refer to the EPA's Technical Support Document for more detailed information.

The EPA believes that all NO_X exemptions that are approved should be approved only on a contingent basis. As described in the EPA's NO_X Supplement to the General Preamble (57 FR 55628, November 25, 1992), the EPA would rescind a NO_X exemption in cases where NO_X reductions were later found to be beneficial in the area's attainment plan. That is, a modeling based exemption would last for only as long as the area's modeling continued to demonstrate attainment without the additional NO_X reductions.

If the EPA later determines that additional NO_X reductions from transportation sources are beneficial based on new photochemical grid modeling in an area initially exempted, the area would be removed from exempt status and would be required to implement the NO_X provisions of the transportation conformity rule except to the extent that modeling shows NO_X reductions to be ''excess reductions.''

In summary, the UAM modeling results for the Baton Rouge nonattainment area indicate that additional NO_X reductions as well as NSR control of any NO_X increases related to expected growth would not contribute to attainment of the ozone standard by 1999. The EPA therefore proposes to approve the transportation conformity NO_X exemption for the Baton Rouge area. This exemption will remain effective for only as long as modeling continues to show that NO_X control of transportation sources would not contribute to attainment in the Baton Rouge nonattainment area.

Proposed Rulemaking Action and Solicitation of Comments

Based on the State's SIP revision request and associated documentation, the EPA proposes to approve Louisiana's request for an exemption from the transportation conformity NO_X requirements.

Public comments are solicited on the requested SIP revision and on EPA's proposed rulemaking action. Comments received by November 6, 1995, will be considered in the development of the EPA's final rule.

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995, memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

Nothing in this action should be construed as permitting, allowing, or establishing a precedent for any future request for revision to any SIP. The EPA shall consider each request for revision to the SIP in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, the EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities (5 U.S.C. 603 and 604). Alternatively, the EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

This approval does not create any new requirements. Therefore, I certify that this action does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of the regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of the State action. The Act forbids the EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A*, 427 U.S. 246, 256–66 (1976).

Under section 202 of the Unfunded Mandates Reform Act of 1995, (''Unfunded Mandates Act''), signed into law on March 22, 1995, the EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, the EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires the EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. The EPA has determined that this action does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector.

This Federal action will relieve requirements otherwise imposed under the Act, and hence does not impose any Federal intergovernmental mandate, as defined in section 101 of the Unfunded Mandates Act. Accordingly, no additional costs to State, local, or tribal governments, or the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Conformity, Intergovernmental relations, Oxides of nitrogen, Ozone, Transportation conformity.

Authority: 42 U.S.C. 7401–7671q.

Dated: September 29, 1995.

Samuel Coleman,

Acting Regional Administrator.

[FR Doc. 95–24939 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 52

[FRL–5309–6]

Clean Air Act Promulgation of Extension of Attainment Date for PM–10 Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to grant a 1-year attainment date extension for the Denver, Colorado particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM–10) nonattainment area. This proposed action is based on monitored air quality data for the national ambient air quality standard for PM–10 during the years 1992–94 and EPA's evaluatation of the applicable state implementation plan (SIP).

In the Final Rules Section of the Federal Register, EPA is granting the State's extension request, as a direct final rule without prior proposal because the Agency views this as a noncontroversial action and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed rule must be received in writing by November 6, 1995.

ADDRESSES: All written comments should be addressed to: Douglas M. Skie, Chief, Air Programs Branch, EPA Region VIII, at the address listed below. Information supporting this action can be found at the following location: EPA Region VIII, Air Programs Branch, 999 18th Street, Denver, Colorado 80202–2466; and Colorado Air Pollution Control Division, 4300 Cherry Creek Drive South, Denver, Colorado 80222–1530. The information may be inspected between 8 a.m. and 4 p.m., on weekdays, except for legal holidays. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Callie Videtich, Air Programs Branch, EPA Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202–2405, (303) 293–1754.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule which is located in the Rules Section of this Federal Register.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Authority: 42 U.S.C. 7401–7671q.

Dated: September 25, 1995.

Jack W. McGraw,

Acting Regional Administrator.

[FR Doc. 95–24509 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[LA–14–1–5941; FRL–5310–1]

Clean Air Act Approval and Promulgation of New Source Review; Implementation Plan Addressing New Source Review in Nonattainment Areas; Louisiana; Approval and Promulgation of Air Quality Implementation Plans; Louisiana Administrative Code (LAC), Title 33, Environmental Quality, Part III. Air, Chapter 5. Permit Procedures, Section 504. Nonattainment New Source Review (NSR) Procedures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes approval of the State Implementation Plan (SIP) revision, submitted by the State of Louisiana for the purpose of meeting requirements of the Clean Air Act (Act or CAA), as amended in 1990, with regard to NSR in areas that have not attained the national ambient air quality standards (NAAQS).

DATES: Comments on this proposed action must be received in writing on or before November 6, 1995.

ADDRESSEES: Written copies on this action should be addressed to Ms. Jole C. Luehrs, Chief, Air Permits Section, at the EPA Regional Office listed below. Copies of the documents relevant to this proposed action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

U.S. Environmental Protection Agency, Region 6, Multimedia Planning and Permitting Division (6PD), 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733

Louisiana Department of Environmental Quality, H. B. Garlock Building, 7290 Bluebonnet Boulevard, Baton Rouge, Louisiana 70810.

FOR FURTHER INFORMATION CONTACT: Mr. Richard A. Barrett, Air Permits Section (6PD-R), Multimedia Planning and Permitting Division, U.S. EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7227, facsimile (214) 665–2164.

SUPPLEMENTARY INFORMATION:

I. Background

The air quality planning requirements for nonattainment new source review are set out in part D of Title I of the CAA, as amended in 1990. The EPA has issued a ''General Preamble'' describing the EPA's preliminary views on how the EPA intends to review SIPs and SIP revisions submitted under part D; including those State submittals containing nonattainment area NSR SIP requirements [see 57 FR 13498 (April 16, 1992) and 57 FR 18070 (April 28, 1992)]. Because the EPA is describing its interpretations here only in broad terms, the reader should refer to the General Preamble for a more detailed discussion of the interpretations of part D advanced in this proposal and the supporting rationale. The EPA is currently developing a proposed rule to implement the changes under the 1990 Amendments in the NSR provisions in parts C and D of Title I of the Act. The EPA anticipates that the proposed rule will be published for public comment in 1995. If the EPA has not taken final action on States' NSR submittals by that time, the EPA will refer to the proposed rule as the most authoritative guidance available regarding the approvability of the submittals. The EPA expects to take final action to promulgate a final rule to implement the parts C and D changes sometime during 1996. Upon promulgation of those regulations, the EPA will review those NSR SIP submittals, on which it has taken final action, to determine whether additional SIP revisions are necessary.

Prior to EPA approval of a State's NSR SIP submission, the State may continue permitting only in accordance with the new statutory requirements for permit applications completed after the relevant SIP submittal date. This policy was explained in transition guidance memoranda from John Seitz dated March 11, 1991, ''New Source Review (NSR) Program Transitional Guidance'', and September 3, 1992, ''New Source Review (NSR) Program Supplemental Transitional Guidance on Applicability of New Part D NSR Permit Requirements''.

As explained in the memorandum of March 11, 1991, the EPA does not believe Congress intended to mandate the more stringent Title I NSR requirements during the time provided for SIP development. States were thus allowed to continue to permit consistent with requirements in their current NSR SIPs during that period, or apply 40 CFR part 51, Appendix S for newly designated areas that did not previously have NSR SIP requirements.

The September 3, 1992, memorandum also addressed the situation where States did not submit the part D NSR SIP requirements or revisions by the applicable statutory deadline. For permit applications complete by the SIP submittal deadline, States may issue final permits under the prior NSR rules,

assuming certain conditions in the September 3 memorandum are met. However, for applications completed after the SIP submittal deadline, the EPA will consider the source to be in compliance with the Act where the source obtains from the State a permit that is consistent with the substantive new NSR part D provisions in the Act. The EPA believes this guidance continues to apply to permitting pending final action on NSR SIP submittals.

II. Proposed Rulemaking Action

A. Procedural Background

The Act requires States to observe certain procedural requirements in developing implementation plans and plan revisions for submission to the EPA. Section 110(a)(2) of the Act, 42 U.S.C. 7410(a)(2), provides that each implementation plan submitted by a State must be adopted after reasonable notice and public hearing.[1] Section 110(l) of the Act similarly provides that each revision to an implementation plan submitted by a State under the Act must be adopted by such State after reasonable notice and public hearing.

After adequate public notice, the State of Louisiana held a public hearing, on December 30, 1992, to entertain public comment on the NSR implementation plan, which replaced the emergency rules submitted to the EPA on November 10, 1992. Following the public hearing, the plan was adopted by the State on February 20, 1993, and submitted to the EPA on March 3, 1993, as a proposed revision to the SIP. The State submitted, to the EPA, revisions for the Louisiana SIP to implement the NSR requirements of the CAA in nonattainment areas in Louisiana. Louisiana made the SIP revision to LAC Title 33, Part III, Chapter 5. Permit Procedures, by the addition of section 504. Nonattainment New Source Review Procedures. The SIP revision was reviewed by the EPA to determine administrative completeness shortly after its submittal. The completeness review was based upon the criteria as set out at 40 CFR part 51 Appendix V. The submittal was found to be complete on July 10, 1993; and a letter dated August 3, 1993, was forwarded to the Governor indicating the completeness of the submittal and the next steps to be taken in the review process. Prior to the EPA acting on these revisions, the State submitted a notice of adoption and final rule on Regulation LAC 33:III.Chapter 5, which included and amended section 504, on November 15, 1993, in order to meet the requirements mandated by sections 173 and 182 of the Act. This proposed rule applies to, and contains an evaluation of, section 504.

In this action, the EPA proposes approval of the Louisiana nonattainment NSR SIP rules identified in this notice, and invites public comment on the action. Those sections submitted to the EPA not included in the revisions specifically addressed in this proposal will be the subject of a future rulemaking. In this rulemaking action on the Louisiana nonattainment NSR SIP, the EPA is proposing to apply its interpretations, taking into consideration the specific factual issues presented. Thus, the EPA will consider any timely submitted comments prior to the EPA's taking final action on this proposed rule.

B. General Nonattainment NSR Requirements

The statutory requirements for nonattainment NSR SIPs and permitting are found at sections 172 and 173.

The Act requires all States to have submitted, at a minimum, the following nonattainment NSR provisions by November 15, 1992:

1. Provisions to assure that calculation of emissions offsets, as required by section 173(a)(1)(A), are based on the same emissions baseline used in the demonstration of reasonable further progress. Louisiana has established provisions to satisfy this section pursuant to sections 504.F.4 and 504.F.5.

2. Provisions to allow, according to section 173(c)(1), offsets to be obtained in another nonattainment area if: the area in which the offsets are obtained has an equal or higher nonattainment classification; and emissions from the nonattainment area, in which the offsets are obtained, contribute to a National Ambient Air Quality Standards (NAAQS) violation, in the area in which the source would construct. Louisiana has established provisions to satisfy this section, pursuant to section 504.F.9.

3. Provisions to assure, according to section 173(c)(1), that any emissions offsets, obtained in conjunction with the issuance of a permit to a new or modified source, must be in effect and enforceable by the time the new or modified source is to commence operation. Louisiana has established provisions to satisfy this section pursuant to section 504.F.3.

4. Provisions to assure that emissions increases, from new or modified major stationary sources, are offset by real reductions in actual emissions, as required by section 173(c)(1). Louisiana has established provisions to satisfy this section pursuant to sections 504.D.3 and 504.F.7.

5. Provisions, according to section 173(c)(2), to prevent emissions reductions, otherwise required by the Act, from being credited for purposes of satisfying the part D offset requirements. Louisiana has established provisions to satisfy this section pursuant to sections 504.F.5. and 504.F.10.

6. Provisions, according to section 173(a)(5), that, as a prerequisite to issuing any part D permit, require an analysis of alternative sites, sizes, production processes, and environmental control techniques for proposed sources that demonstrates that the benefits of the proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification. Louisiana has established provisions to satisfy this section pursuant to section 504.D.6.

7. Provisions, according to section 173(e), that allow any existing or modified source, that tests rocket engines or motors, to use alternative or innovative means to offset emissions increases from firing and related cleaning, if four conditions are met: (a) the proposed modification is for expansion of a facility already permitted for such purposes; (b) the source has used all available offsets and all reasonable means to obtain offsets and sufficient offsets are not available; (c) the source has obtained a written finding by the appropriate, sponsoring Federal agency that the testing is essential to national security; and (d) the source will comply with an alternative measure designed to offset any emissions increases not directly offset by the source.

In lieu of imposing any alternative offset measures, the permitting authority may impose an emission offset amounting to no more than 1.5 times the average cost of stationary control measures adopted in that area during the previous three years. Louisiana has established provisions to satisfy this section pursuant to section 504.D.7.

8. Provisions, according to section 173(a)(3), to assure that owners or operators, of each proposed new or modified major stationary source, demonstrate that all other major stationary sources, under the same ownership in the State, are in compliance with the Act. Louisiana has established provisions to satisfy this section pursuant to section 504.D.1.

9. Provisions, according to section 173(a)(2), to assure that permits for new and modified major stationary sources to construct and operate may be issued

[1] Section 172(c)(7) of the Act provides that plan provisions for nonattainment areas shall meet the applicable provisions of Section 110(a)(2).

if the proposed source is required to comply with the lowest achievable emission rate. Louisiana has established provisions to satisfy this requirement pursuant to section 504.D.2.

10. Additionally, the State must assure that no interpollutant trading is allowed as defined in 40 CFR part 51, Appendix S, section IV, condition 3. Louisiana has established provisions to satisfy this requirement pursuant to section 504.F.1.

11. The public notice and participation requirements, previously located in Section 504, have now been placed in LAC 33:III. Chapter 5. Section 531, which will be acted on by the EPA in a future rulemaking action. These requirements were located in the March 3, 1993, submittal and were subsequently moved in the November 15, 1993, submittal to Section 531. Public participation requirements have previously been approved in the SIP.

C. Ozone

The general nonattainment NSR requirements are found in sections 172 and 173 of the Act and must be met by all nonattainment areas. Requirements for ozone that supplement or supersede these requirements are found in subpart 2 of part D. In addition, subpart 2 includes section 182(f), which states that requirements, for major stationary sources of volatile organic compounds (VOC), shall apply to major stationary sources of oxides of nitrogen (NO_X) unless the Administrator makes certain determinations related to the benefits or contribution of NO_X control to air quality, ozone attainment, or ozone air quality. States were required under section 182(a)(2)(C) to adopt new NSR rules for ozone nonattainment areas by November 15, 1992.

1. Marginal Ozone Nonattainment Areas

For marginal ozone nonattainment areas, States must submit the following NSR provisions:

a. Definition of the term ''major stationary source'' that reflects the section 302(j) 100 tons per year (tpy) VOC and, presumptively, the 100 tpy NO_X threshold for determination of whether a source is subject to part D NSR requirements as a major source.

b. Provisions to ensure that new or modified major stationary sources obtain offsets under section 182(a)(4) at a ratio of at least 1.1 to 1 in order to obtain an NSR permit.

2. Moderate Ozone Nonattainment Areas

For moderate ozone nonattainment areas, States must submit the following NSR provisions:

a. Definition of the term ''major stationary source'' that reflects the section 302(j) 100 tpy VOC and, presumptively, the 100 tpy NOx threshold for determination of whether a source is subject to part D NSR requirements as a major source.

b. Provisions to ensure that new or modified major stationary sources obtain offsets under section 182(a)(4) at a ratio of at least 1.15 to 1 in order to obtain an NSR permit.

3. Serious Ozone Nonattainment Areas

For serious ozone nonattainment areas, States must submit the following NSR provisions:

a. Definition of the term ''major stationary source'' that reflects the section 182(c) 50 tpy VOC and, presumptively, the 50 tpy NO_X threshold for determination of whether a source is subject to part D requirements as a major source.

b. Provisions to ensure that new or modified major stationary sources obtain offsets under section 182(c)(10) at a ratio of at least 1.2 to 1 in order to obtain an NSR permit.

c. Provisions to implement section 182(c)(6) of the Act such that any proposed emissions increase is subject to the 25-ton de minimis test over a five year period.

4. Severe Ozone Nonattainment Areas

For severe ozone nonattainment areas, States must submit the following NSR provisions:

a. Definition of the term ''major stationary source'' that reflects the section 182(d) 25 tpy VOC and, presumptively, the 25 tpy NO_X threshold for determination of whether a source is subject to part D requirements as a major source.

b. Provisions to ensure that new or modified major stationary sources obtain offsets at a ratio [under section 182(d)(2)] of at least 1.3 to 1 in order to obtain an NSR permit, unless the SIP requires all existing major sources in the nonattainment area to use Best Available Control Technology, in which case, the offset ratio is at least 1.2 to 1.

c. Provisions to implement section 182(c)(6) of the Act such that any proposed emissions increase is subject to the 25-ton de minimis test over a five year period.

Louisiana has established major source thresholds and offset ratios for VOC and included provisions for NO_X major stationary sources as follows:

Area classification	Major source threshold	Offset ratio minimum	NO_X provisions
Marginal	100 tpy	1.10 to 1	See paragraph below.
Moderate	100 tpy	1.15 to 1	Identical to VOC.
Serious	50 tpy	1.20 to 1	Identical to VOC, see paragraph below.
Severe	25 tpy	1.30 to 1	Identical to VOC.
Extreme	Not applicable	Not applicable	Not applicable.

The EPA is currently evaluating a petition for exemption from NO_X requirements pursuant to section 182(f), received on October 28, 1994, from the State of Louisiana. The petition regarding the NO_X offset requirement for the marginal ozone nonattainment area of Calcasieu Parish, Louisiana, will be the subject of future EPA action. If this petition is approved, the EPA intends to publish final approval of the NSR SIP. If the petition is not approved, the EPA will readdress the NSR SIP to require NO_X offsets in the marginal ozone nonattainment areas of Louisiana.

The EPA has proposed approval of a petition for exemption from NO_X requirements pursuant to section 182(f), received from the State of Louisiana on November 17, 1994, for the serious ozone nonattainment area of Baton Rouge, and has proposed its approval on August 18, 1995 (see 60 FR 43100). If approved, NO_X offsets will not be required in that area.

Louisiana has established all of the above requirements for all other ozone nonattainment areas.

Additionally, for nonclassifiable (transitional or incomplete data) ozone nonattainment areas, State rules for the marginal area classification apply. For further information on nonclassifiable areas see, ''General Preamble'' 57 Federal Register 55624 (April 16, 1992), and the ''NO_X supplement to the General Preamble'' 57 FR 13523 (November 25, 1993).

In addition, Louisiana's plan submittal reflects appropriate modification provisions, including a de minimis level of 25 tons.

D. Carbon Monoxide (CO)

The general part D NSR permit requirements apply in CO nonattainment areas, and are supplemented by the CO requirements in subpart 3 of part D.

1. All moderate CO nonattainment areas, with a design value of 12.7 parts per million or less, must submit proposed part D NSR programs no later than November 15, 1993. Such programs must have the following provisions:

a. Definition of the term ''major stationary source'' that reflects the section 302(j) 100 tpy CO threshold for determination of whether a source is subject to part D requirements as a major source.

b. Provisions to ensure that new or modified major stationary sources obtain offsets under section 173(a)(1)(A) at a ratio of at least 1 to 1 in order to obtain an NSR permit.

2. All States, with moderate CO nonattainment areas with a design value greater than 12.7 ppm, were required to submit proposed part D NSR programs by November 15, 1992. Such programs must have the following provisions:

a. Definition of the term ''major stationary source'' that reflects the 100 tpy CO threshold for determination of whether a source is subject to part D requirements as a major source.

b. Provisions to ensure that new or modified major stationary sources obtain offsets at a ratio of at least 1 to 1 in order to obtain an NSR permit.

3. Pursuant to section 187(c)(1), 42 U.S.C. 7512a(c)(1), all States with serious CO nonattainment areas, in which stationary sources contribute significantly to CO levels (as determined under rules issued by the Administrator; i.e., according to guidance issued in a May 13, 1991, memorandum ''Guidance for Determining Significant Stationary Sources for Carbon Monoxide'' from William Laxton, Director, Technical Support Division to Regional Air Division Directors) were required to submit part D NSR programs by November 15, 1992. Such programs must have the following provisions:

a. Definition of the term ''major stationary source'' that reflects the 50 tpy CO threshold for determination of whether a source is subject to part D requirements as a major source.

b. Provisions under section 173(a)(1)(A) to ensure that new or modified major stationary sources obtain offsets at a ratio of at least 1 to 1 in order to obtain an NSR permit.

4. All States with nonclassifiable CO nonattainment areas must submit revised part D programs by November 15, 1993.

Louisiana has established a major source threshold of 100 tpy, and a minimum offset ratio of greater than 1.00 to 1 for moderate CO nonattainment areas. Louisiana has established a major source threshold of 50 tpy, and a minimum offset ratio of greater than 1.00 to 1 for serious nonattainment areas.

Louisiana has no areas designated as nonattainment for CO at this time.

E. Particulate Matter Less Than 10 Micrometers In Diameter (PM–10)

Pursuant to section 189(a)(2) 42 U.S.C. 7513a(a)(2), all States, with a PM–10 nonattainment area classified as moderate, were required to submit an NSR permit program SIP revision by June 30, 1992, or 18 months after the designation of such an area.

1. Moderate Areas

PM–10 NSR programs must have the following provisions:

a. Definition of the term ''major stationary source'' that reflects thresholds in section 302(j) of 100 tpy for PM–10 and, presumptively, 100 tpy for each PM–10 precursor for determination of whether a source is subject to part D requirements as a major source.

b. Provisions under section 173(a)(1)(A) to ensure that new or modified major stationary sources obtain emission offsets at an offset ratio of at least 1 to 1.

c. Under section 189(e), requirements applicable to major sources of PM–10 are also applicable to major sources of PM–10 precursors, except where the Administrator determines that such sources do not contribute significantly to PM–10 levels which exceed the standards in the area. The EPA generally considers sulfur dioxide, nitrogen oxides, or volatile organic compounds to be PM–10 precursors for NSR purposes in certain areas. Further guidance on making such determinations has been issued at 57 Federal Register 13541 (April 16, 1992) and 57 Federal Register 18070 (April 28, 1992).

d. Provisions to ensure that the significance threshold for a modification to be major, and therefore subject to the section 173 permit requirements, is 15 tpy for PM–10 and, presumptively, 15 tpy for each PM–10 precursor.

2. Serious Areas

PM–10 NSR programs must have the following provisions:

a. Definition of the term ''major stationary source'' that reflects the section 189(b)(3) thresholds of 70 tpy for PM–10 and 70 tpy for each PM–10 precursor (in certain cases) for determination of whether a source is subject to part D requirements as a major source.

b. Provisions under section 173(a)(1)(A) to ensure that new or modified major stationary sources obtain an offset ratio of at least 1 to 1.

c. Under section 189(e), requirements applicable to major sources of PM–10 are also applicable to major sources of PM–10 precursors, except where the Administrator determines that such sources do not contribute significantly to PM–10 levels which exceed the standards in the area.

d. Provisions to ensure that the significance threshold for a modification to be major, and therefore subject to the section 173 permit requirements, is 15 tpy for PM–10 and, presumptively 15 tpy for each PM–10 precursor.

Louisiana has established major source thresholds, offset ratios, modification significance levels, and PM–10 precursor provisions as follows:

Area classification	Major source threshold	Offset ratio minimum	Significance level	Precursor provisions
Moderate	100 tpy	Greater than 1 to 1	15 tpy	See paragraph below.
Serious	50 tpy	Greater than 1 to 1	15 tpy	See paragraph below.

Since Louisiana has no areas designated as nonattainment for PM–10 at this time, the EPA is proposing to approve the PM–10 NSR provisions for the limited purpose of strengthening the SIP and not for satisfying the part D NSR requirements for PM–10. If an area is designated nonattainment for PM–10, then the State would be required to submit provisions for PM–10 precursors unless it has sought and obtained a determination by the EPA under section 189(e).

F. Sulfur Dioxide (SO_2)

States with SO_2 nonattainment areas were required to submit NSR implementation plans by May 15, 1992. States with areas that are designated or redesignated as nonattainment after the Amendments have 18 months to submit such plans. NSR implementation plans must contain the following provisions with regard to SO_2:

1. Definition of the term ''major stationary source'' that reflects the section 302(j) 100 tpy SO_2 threshold for determination of whether a source is subject to part D requirements as a major source.

2. Provisions under section 173(a)(1)(A) to ensure that new or modified major stationary sources obtain SO_2 offsets at a ratio of at least 1 to 1 in order to obtain an NSR permit.

3. Provisions to ensure that the significance threshold for a modification to be major, and therefore subject to the section 173 permit requirements, is 40 tpy of SO_2.

Louisiana has established a major source threshold of 100 tpy, a minimum offset ratio of greater than 1 to 1, and a modification significance level of 40 tpy.

Louisiana has no areas designated as nonattainment for SO_2 at this time.

G. Lead

Generally, the date, by which a plan must be submitted for an area, is triggered by the area's nonattainment designation. For areas designated nonattainment for the primary lead NAAQS in effect at enactment of the 1990 Amendments; under section 171(b), States must submit SIPs which meet the applicable requirements of part D within 18 months of the date of enactment of the 1990 Amendments. States with lead nonattainment areas are required to submit NSR implementation plans which must contain the following provisions:

1. Definition of the term ''major stationary source'' that reflects the section 302(j) 100 tpy lead threshold for determination of whether a source is subject to part D requirements as a major source.

2. Provisions under section 173(a)(1)(A) to ensure that new or modified major stationary sources of lead obtain lead offsets at a ratio of at least 1 to 1 in order to obtain an NSR permit.

3. Provisions to ensure that the significance threshold for a modification to be major, and therefore subject to the section 173 permit requirements, is 0.6 tpy of lead.

Louisiana has established a major source threshold of 100 tpy, a minimum offset ratio of greater than 1 to 1, and a modification significance level of 0.6 tpy.

Louisiana has no areas designated as nonattainment for Lead at this time.

III. Implications of this Action

The EPA is proposing approval of the plan revisions submitted on March 3, 1993, as amended on November 15, 1993, regarding NSR, subject to EPA approval of the NO_X exemption request for the Calcasieu Parish ozone nonattainment area. The State of Louisiana has submitted a complete plan to implement the NSR provisions of part D. Assuming approval of the NO_X exemption request, each of the program elements mentioned above were properly addressed, with the exception of PM–10 precursor requirements. Since Louisiana has no areas designated as nonattainment for PM–10 at this time, the EPA is proposing to approve the PM–10 NSR provisions for the limited purpose of strengthening the SIP and not for satisfying the part D NSR requirements for PM–10. If an area is designated nonattainment for PM–10, then the State would be required to submit provisions for PM–10 precursors unless it has sought and obtained a determination by the EPA under section 189(e).

Those sections submitted to the EPA, not included in the revisions specifically addressed in this proposal, will be the subject of a future rulemaking. If the EPA does not approve the NO_X exemption request for Calcasieu Parish, there will not be final approval of the NSR SIP until rule changes requiring NO_X offsets in marginal areas are submitted by the State.

Louisiana LAC 33:III.Chapter 5.section 504 is approvable under the requirements for nonattainment area permitting regulations as outlined in 40 CFR part 51 and in part D. These revisions incorporate requirements of the CAA for the construction and operation of new and modified major stationary sources of air pollutants. However, the EPA is currently in the process of revising its regulations, in accordance with the CAA, and expects to propose an amended 40 CFR 51.165 within the near future. These revisions to 40 CFR 51.165 will reflect the new nonattainment NSR provisions added by the CAA in part D, subparts 1 and 2. Once the EPA promulgates final nonattainment NSR rules pursuant to the CAA, the State of Louisiana will have to review LAC 33:III.Chapter 5.section 504 against the requirements found in the final promulgated regulations and submit any additionally required revisions to the EPA for approval.

IV. Request for Public Comments

The EPA is requesting comments on all aspects of the requested SIP revision and the EPA's proposed rulemaking action. Comments received by date indicated above will be considered in the development of the EPA's final rule.

V. Executive Order (EO) 12866

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995, memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget has exempted this regulatory action from EO 12866 review.

VI. Regulatory Flexibility

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., the EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities (5 U.S.C. 603 and 604). Alternatively, the EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals, under section 110 and subchapter I, part D, of the CAA, do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The CAA forbids the EPA to base its actions concerning SIPs on such grounds (*Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (1976); 42 U.S.C. 7410(a)(2)).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals, for the appropriate circuit, by December 5, 1995. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and

shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

VII. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, the EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, the EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires the EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that this proposed action does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, New source review, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Authority: 42 U.S.C. 7401–7671q.

Dated: September 29, 1995.

Samuel Coleman,

Acting Regional Administrator (6RA).

[FR Doc. 95–24940 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 82

[FRL–5313–1]

Protection of Stratospheric Ozone: Listing of Global Warming Potential for Ozone-Depleting Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed listing.

SUMMARY: With this proposed action, the Environmental Protection Agency (EPA or the Agency) lists the global warming potentials for ozone-depleting substances that are included as class I and class II controlled substances, or have been added as class I or class II controlled substances, under authority of section 602(e) of the Clean Air Act Amendments of 1990 (CAA). Class I and class II controlled substances are more fully described in a final rule previously published in the Federal Register on May 10, 1995. To meet EPA's statutory obligation under the CAA, this proposed listing cites the global warming potentials contained in the document, Scientific Assessment of Ozone Depletion: 1994, published by the United Nations Environment Programme (UNEP) in early 1995. As stated in the CAA, the listing of global warming potentials for class I and class II controlled substances ''shall not be construed to be the basis of any additional regulation under this Act.''

DATES: Written comments on this proposed listing must be received on or before November 6, 1995. Inquiries regarding public comments should be directed to the Stratospheric Ozone Information Hotline at 1–800–296–1996.

ADDRESSES: Comments on this proposed listing should be submitted in duplicate (two copies) to: Air Docket No. A–92–13, U.S. Environmental Protection Agency, 401 M Street, SW., Room M–1500, Washington, DC 20460.

Materials relevant to this proposed listing are contained in Docket No. A–92–13. The Docket is located in room M–1500, First Floor, Waterside Mall at the address above. The materials may be inspected from 8 a.m. until 5:30 p.m. Monday through Friday. A reasonable fee may be charged by EPA for copying the docket.

FOR FURTHER INFORMATION CONTACT: Tom Land, Program Implementation Branch, Stratospheric Protection Division, Office of Atmospheric Programs, Office of Air and Radiation (6205J), 401 M Street, SW., Washington, DC 20460, (202) 233–9185. The Stratospheric Ozone Hotline at 1–800–296–1996 can also be contacted for further information.

SUPPLEMENTARY INFORMATION:

I. Background

The temperature of the earth is determined by a balance between incoming energy from the sun and outgoing energy radiated from the earth's surface and atmosphere. Ultraviolet and visible radiation from the sun pass through the earth's atmosphere and strike the earth's surface. The earth radiates this energy from the sun back into the atmosphere in the form of infrared radiation in a process called radiative forcing. Certain constituents of the atmosphere, such as carbon dioxide and water vapor, absorb the infrared radiation and trap it in the atmosphere in a process known as the greenhouse effect. The trapped infrared radiation warms the earth's surface and the troposphere (lower atmosphere). The warming of the earth's surface and the troposphere through the balance between absorbed energy and radiated energy determines the climate of the planet.

The molecular structure of a chemical determines its ability to absorb infrared radiation in the atmosphere. Scientists use an index called the global warming potential (GWP) to quantify the relative capability of different chemicals to absorb radiated infrared radiation. Three factors contribute to a chemical's relative contribution to this radiative forcing process. The three factors are the primary input in the formulation, calculation and use of the radiative forcing index known as the GWP. The three factors that contribute to the relative radiative forcing potential of a chemical are: (1) The capacity to absorb the different wavelengths of infrared energy, (2) the residence time in the atmosphere, and (3) the time period over which the radiative effects will be considered. The first two of these factors are technical, and the third is dependent on the interests of the user. In addition to these direct radiative effects, some chemicals, such as ozone-depleting substances, have an indirect effect on radiative forcing due to interactive atmospheric processes.

Molecules containing carbon-chlorine bonds and carbon-fluorine bonds, such as the ozone-depleting substances controlled under the Montreal Protocol and Title VI of the Clean Air Act Amendments of 1990, absorb radiation emitted by the earth that would otherwise escape into space. In defining the relative capability of ozone-depleting substances to affect radiative forcing, scientists assign a GWP to a specific substance, such as dichlorodifluoromethane (CFC–12). Research to define the GWP for each of

the class I and class II ozone-depleting substances, as well as other substances, is being conducted by scientists throughout the world. The potential of chlorofluorocarbons (CFCs) to provide significant radiative warming to the troposphere has been understood for more than 15 years. However, the exact radiative forcing effect of CFCs and other ozone-depleting substances relative to other chemicals is still being investigated. Scientists are still researching the interaction between atmospheric processes, seasonality, long-term changes in climate, the introduction of chemicals produced by humans into the atmosphere and the uncertainties inherent in the interaction of these complex processes.

II. Referencing Recently Published Scientific Documents

EPA believes that three recently published scientific documents represent the most up-to-date international scientific knowledge regarding GWPs for class I and class II controlled substances. EPA referencing these three scientific documents and the list of GWPs they contain in order to meet the Agency's statutory obligations under Section 602(e) of the CAA to publish GWPs for class I and class II controlled substances. These documents are also referenced in part, for their discussions of different radiative forcing indices and the indirect effects of ozone-depleting substances on radiative forcing. These documents demonstrate the current state of knowledge and the current uncertainties involved in calculating the GWPs for class I and class II controlled substances.

The citation for the three scientific documents that report on GWPs for class I and class II controlled substances are:

United Nations Environment Programme (UNEP), February 1995, Scientific Assessment of Ozone Depletion: 1994, Chapter 13: ''Ozone Depleting Potentials, Global Warming Potentials and Future Chlorine/Bromine Loading;''

Intergovernmental Panel on Climate Change (IPCC), 1995, Climate Change 1994: Radiative Forcing of Climate Change and An Evaluation of the IPCC IS92 Emission Scenarios, ''Summary for Policymakers: Radiative Forcing of Climate Change,'' pages 32–34; and

Daniel, John S., Susan Solomon and Daniel L. Albritton, January 20, 1995, Journal of Geophysical Research, Vol. 100, No. D1, ''On the evaluation of halocarbon radiative forcing and global warming potentials.''

Chapter 13 in the UNEP, Scientific Assessment and pages 32 through 34 in the IPCC, Summary for Policymakers describe the factors considered in calculating various radiative forcing indices, such as (1) the direct GWP, (2) the absolute global warming potential (AGWP), and (3) the net GWP per unit mass emission. Chapter 13 of the Scientific Assessment and the article by John S. Daniel, et. al. in the Journal of Geophysical Research describe the indirect feedback effects of ozone-depleting substances on the temperature of the atmosphere, and therefore the potential indirect effects that depletion of stratospheric ozone has on the calculation of the GWP.

III. Listing GWPs for class I and class II Controlled Substances

With today's action, EPA proposes publication of the GWPs that are listed for class I and class II controlled substances in the Scientific Assessment of Ozone Depletion: 1994 as published by the United Nations Environment Programme (UNEP) under the auspices of the Montreal Protocol in February of 1995. The GWPs for class I and class II controlled substances as published in the Scientific Assessment are in Appendix I to Subpart A—Global Warming Potentials.

The Scientific Assessment of Ozone Depletion: 1994 does not list a GWP for every controlled substance that is listed in Appendices A and B to Subpart A as most recently promulgated in the Federal Register on May 10, 1995 (60 FR 24970). For some ozone-depleting chemicals, such as methyl bromide, scientists have not developed a full infrared spectrum that is necessary to calculate the relative radiative forcing potential of a substance. Each chemical absorbs the Earth-emitted infrared radiation in specific energy (or wavelength) bands determined by the quantum-mechanical properties of the specific molecule.[1] Scientists have not measured the spectral region in which some of the ozone-depleting substances absorb infrared radiation. In addition, more data must be collected on the tropospheric distribution and concentration of some of the chemicals, their atmospheric lifetimes, and the interactive atmospheric chemistry in order to complete a calculation of the global warming potential for the remaining ozone-depleting substances. Scientific centers and academic institutions throughout the world are undertaking the necessary measurements and studies that are needed to complete the calculations of GWPs for other ozone-depleting substances. EPA believes it is not possible at this time to publish GWPs for every ozone-depleting substance listed in Appendix A and B to Subpart A because the necessary scientific information is not available. EPA will continue to evaluate GWPs for class I and class II controlled substances not listed in today's proposal and as deemed appropriate amend the listing through rule making.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Exports, Hydrochlorofluorocarbons, Imports, Ozone layer, Reporting and recordkeeping requirements, Stratospheric ozone layer.

Dated: September 29, 1995.

Carol Browner,

Administrator.

40 CFR part 82 is proposed to be 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. 7414, 7601, 7671–7671q.

2. Appendix I is added to Subpart A to read as follows:

APPENDIX I TO SUBPART A—GLOBAL WARMING POTENTIALS (Mass Basis), REFERENCED TO THE ABSOLUTE GWP FOR THE ADOPTED CARBON CYCLE MODEL CO_2 DECAY RESPONSE AND FUTURE CO_2 ATMOSPHERIC CONCENTRATIONS HELD CONSTANT AT CURRENT LEVELS

[Only direct effects are considered]

Species (chemical)	Chemical formula	Global warming potential (time horizon)		
		20 years	100 years	500 years
CFC–11	$CFCl_3$	5000	4000	1400

[1] Wuebbles, Donald J., 1995, ''Weighing Functions for Ozone Depletion and Greenhouse Gas Effects on Climate,'' Annual Review of Energy and Environment, 20:45–70.

APPENDIX I TO SUBPART A—GLOBAL WARMING POTENTIALS (Mass Basis), REFERENCED TO THE ABSOLUTE GWP FOR THE ADOPTED CARBON CYCLE MODEL CO_2 DECAY RESPONSE AND FUTURE CO_2 ATMOSPHERIC CONCENTRATIONS HELD CONSTANT AT CURRENT LEVELS—Continued

[Only direct effects are considered]

Species (chemical)	Chemical formula	Global warming potential (time horizon)		
		20 years	100 years	500 years
CFC–12	CF_2Cl_2	7900	8500	4200
CFC–13	$CClF_3$	8100	11700	13600
CFC–113	$C_2F_3Cl_3$	5000	5000	2300
CFC–114	$C_2F_4Cl_2$	6900	9300	8300
CFC–115	C_2F_5Cl	6200	9300	13000
H–1301	CF_3Br	6200	5600	2200
Carbon Tet	CCl_3	2000	1400	500
Methyl Chl	CH_3CCl_3	360	110	35
HCFC–22	CF_2HCl	4300	1700	520
HCFC–141b	$C_2FH_3Cl_2$	1800	630	200
HCFC–142b	$C_2F_2H_3Cl$	4200	2000	630
HCFC–123	$C_2F_3HCl_2$	300	93	29
HCFC–124	C_2F_4HCl	1500	480	150
HCFC–225ca	$C_3F_5HCl_2$	550	170	52
HCFC–225cb	$C_3F_5HCl_2$	1700	530	170

United Nations Environment Programme (UNEP), February 1995, Scientific Assessment of Ozone Depletion: 1994, Chapter 13, ''Ozone Depleting Potentials, Global Warming Potentials and Future Chlorine/Bromine Loading.''

[FR Doc. 95–24938 Filed 10–5–95; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 25

[CGD 87–016b]

RIN 2115–AC69

Emergency Position Indicating Radio Beacons for Uninspected Vessels

AGENCY: Coast Guard, DOT.

ACTION: Notice of withdrawal.

SUMMARY: This rulemaking was intended to require emergency position indicating radio beacons (EPIRBs) to be carried on certain uninspected passenger vessels and assistance towing vessels. The proposed EPIRB requirements would have applied to vessels operating on the high seas and on the Great Lakes beyond three miles from the coastline. The Coast Guard also proposed requiring visual distress signals on all uninspected vessels not presently required to carry them, when those vessels operate in coastal waters. The Coast Guard has decided to withdraw this project because existing regulations generally fulfill the intended purpose of the underlying statute and the Coast Guard needs to focus its available resources on other regulatory projects.

DATES: This withdrawal is effective on October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Markle, Project Manager, Office of Marine Safety, Security, and Environmental Protection (G–MMS–4), (202) 267–1444.

SUPPLEMENTARY INFORMATION: Public Law 100–540, known as the ''EPIRB's On Uninspected Vessels Requirements Act'' (102 Stat. 2719, October 28, 1988), amended 46 U.S.C. 4102 by revising paragraph (e) to require uninspected commercial vessels operating on the high seas and on the Great Lakes beyond three miles from the coastline to carry the number and type of alerting and locating equipment, including emergency position indicating radio beacons (EPIRBs) as prescribed by the Secretary of Transportation.

On March 10, 1993, the Coast Guard published a Final Rule requiring EPIRBs on certain uninspected vessels, excluding uninspected passenger vessels and assistance towing vessels (58 FR 13364). The preamble of that final rule explained that a Supplemental Notice of Proposed Rulemaking (SNPRM) would propose new EPIRB regulations and visual distress signal requirements for uninspected vessels not presently required to carry them.

On February 17, 1994, the Coast Guard published an SNPRM titled ''Emergency Position Indicating Radio Beacons and Visual Distress Signals for Uninspected Vessels'' (59 FR 8100). The SNPRM proposed EPIRB requirements for a limited category of uninspected passenger vessels and assistance towing vessels, and proposed the carriage of visual distress signals for certain uninspected vessels not currently required to carry them.

The Coast Guard has completed a comprehensive review of its regulations and is withdrawing some proposed regulations resources on the highest priority projects. In reviewing this regulatory project, it was noted that the Coast Guard had required many uninspected vessels to carry EPIRBs under the Final Rule of March 10, 1993, and had therefore largely fulfilled its obligations under P.L. 100–540. The Coast Guard has therefore determined that the best course of action is to withdraw this rulemaking.

Dated: September 26, 1995.

Joseph J. Angelo,

Acting Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 95–24920 Filed 10–5–95; 8:45 am]
BILLING CODE 4910–14–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 36

[CC Docket No. 80–286; FCC 95–416]

Proposed Six-Month Extension of the Interim Indexed Cap on the Total Level of the Universal Service Fund

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Communications Commission proposes to extend the duration of the interim indexed cap on the total level of the Universal Service Fund (USF) for an additional six months. The cap was intended to be

effective as an interim measure moderating the growth of the USF during the pendency of a broader rulemaking revising the Part 36 jurisdictional separations rules governing the USF. The Federal Communications Commission proposes to extend the interim cap, which expires January 1, 1996, for an additional six months while that rulemaking is completed.

DATES: Comments must be filed on or before October 18, 1995, and reply comments must be filed on or before October 27, 1995.

ADDRESSES: Comments should be addressed to Office of the Secretary, Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Deborah A. Dupont, Senior Attorney, 202–418–0873, Accounting and Audits Division, Common Carrier Bureau.

SUPPLEMENTARY INFORMATION:

I. Introduction

In this Notice of Proposed Rulemaking we propose extending the duration of the two-year indexed cap (''interim cap'') on the total level of the Universal Service Fund (''USF'').[1] The cap was intended to be effective as an interim measure moderating the growth of the USF during the pendency of our broader rulemaking revising the Part 36 jurisdictional separations rules governing the USF.[2] We propose to extend the interim cap for an additional six months while we complete that rulemaking.

2. We request comment on our proposed extension of the interim cap. We also refer the proposed extension of the interim cap on the Federal-State Joint Board in this proceeding for a recommended decision, as required by Section 410(c) of the Communications Act of 1934, as amended.[3]

3. To continue to moderate the growth of the USF effectively during the entire rulemaking period, the six-month extension must be effective by the January 1, 1996 expiration[4] of the interim cap. For this reason, and because we are proposing only to extend the current interim rules for a limited duration, we set a relatively short comment cycle. Comments will be due on October 18, 1985, and reply comments will be due on October 27, 1995.

II. Background

4. The USF rules were adopted in 1984 to promote universally available telephone services at reasonable rates.[5] The rules allow local exchange carriers (''LECs'') with an average unseparated loop cost per working loop[6] (''average cost per loop'') above the assistance threshold to allocate a percentage of these costs to the interstate jurisdiction.[7] The current rules offer the most assistance to smaller LEC study areas[8] with higher average cost per loop,[9] although all study areas with average cost per loop above the assistance threshold receive some assistance.[10]

5. In 1993, in response to pronounced and erratic growth in the total level of the USF, we stated our intention to reappraise the USF high-cost assistance mechanisms to determine whether changes were needed to better serve our underlying public policy goals.[11] The completion of the eight-year USF phase-in period and ''numerous regulatory, technological, and market changes in the telecommunications industry'' also supported a reevaluation of the high-cost assistance mechanisms at that time.[12] We intended to address possible changes in the Part 36 USF rules through a notice of proposed rulemaking.[13] An indexed cap on the total level of the USF was imposed for the purpose of moderating growth in the USF for the anticipated duration of that rulemaking period.[14] The interim cap expires on January 1, 1996.[15]

6. In order to focus the issues in advance of the proposed rulemaking,[16] we requested comments on several policy questions relating to the goals and effects of high-cost assistance.[17] We also requested comment on two broad alternative approaches to the high-cost assistance mechanisms of Part 36.[18] Under the first approach, assistance would be based on actual reported costs, as is the case under our present rules.[19] Under the second, proxy factors reasonably correlated with either the need for assistance or with costs would be used to determine assistance.[20]

7. On July 13, 1995, we issued a Notice of Proposed Rulemaking and Notice of Inquiry (''Notice'') proposing revisions to our USF rules. The Notice requested comments by September 12 and reply comments by October 12.[21] The Notice invited comment on three proposals for revising our USF rules.[22] The first proposal presented three specific alternative modifications to the existing rules that would continue to

[1] 47 CFR 36.601(c) (1994). Under the interim cap, growth in the total level of the USF is indexed to growth in the total number of working loops. *Id.*; see also Amendment of Part 36 of The Commission's Rules And Establishment of a Joint Board, Report and Order, 9 FCC Rcd 303, 305, para. 20 (1993) (Interim Order). A working loop is ''[a] revenue producing pair of wires, or its equivalent, between a customer's station and the central office from which the station is served.'' 47 CFR Part 36, Appendix-Glossary (1994).

[2] Interim Order, *supra* note 1, at 303, paras. 1–2.

[3] 47 U.S.C. 410(c).

[4] 47 CFR 36.601(c).

[5] Amendment of Part 67 of the Commission's Rules and Establishment of a Joint Board, Decision and Order, 96 FCC 2d 781, 794, para. 29 (1984).

[6] The costs included in the unseparated loop costs are enumerated in 47 CFR 36.621(a) (1994). The number of working loops within a LEC study area is defined in 47 CFR 36.611(a)(8) (1994). The average unseparated loop cost per working loop and national average unseparated loop cost per working loop are defined in 47 CFR 36.622 (1994).

[7] LECs with average cost per loop above 115% of the national average cost per loop can allocate a specified percentage of these costs to the interstate jurisdiction. 47 CFR 36.631 (c), (d) (1994). This allocation is in addition to the interstate allocation allowed under our general jurisdictional separations rules. See 47 CFR 36.154(c) (1994).

[8] 47 CFR 36.631(c) (allowing LEC study areas with 200,000 or fewer working loops to allocate to the interstate jurisdiction 65% or more of their average cost per loop above 115% of the national average cost per loop) with § 36.631(d) (allowing LEC study areas with greater than 200,000 working loops to allocate to the interstate jurisdiction 60% or more of their average cost per loop above 200% of the national average cost per loop and 10% to 30% of their average cost per loop above 115% and at or below 200% of the national average cost per loop).

[9] Compare 47 CFR 36.631(c)(1) (allowing LEC study areas with 200,000 or fewer working loops to allocate to the interstate jurisdiction 65% of their average cost per loop above 115% and at or below 150% of the national average cost per loop) with § 36.631(c)(2) (allowing LEC study areas with 200,000 or fewer working loops to allocate to the interstate jurisdiction 75% of their average cost per loop above 150% of the national average cost per loop); compare § 36.631(d)(1) (allowing LEC study areas with greater than 200,000 working loops to allocate to the interstate jurisdiction 10% of their average cost per loop above 115% and at or below 160% of the national average cost per loop) with § 36.631(d)(4) (allowing LEC study areas with greater than 200,000 working loops to allocate to the interstate jurisdiction 75% of their average cost per loop above 250% of the national average cost per loop).

[10] LECs of any size with average cost per loop above 115% of the national average cost per loop can allocate some portion of these costs to the interstate jurisdiction. 47 CFR 36.631 (c), (d).

[11] Amendment of Part 36 of The Commission's Rules And Establishment of a Joint Board, Notice of Proposed Rulemaking, FCC Rec 7114, 7114–15, paras. 2, 11–15 (1993) (Interim Notice). 58 FR 48815, September 20, 1993.

[12] Interim Order, *supra* note 1, at 305, para. 15.

[13] *Id.* at 303, paras. 1–2.

[14] *Id.* at 303, para. 1.

[15] 47 CFR 36.601(c).

[16] Amendment of Part 36 of The Commission's Rules And Establishment of a Joint Board, Notice of Inquiry, 9 FCC Rec 7404, 7406 n.5 (1994) 59 FR 46606, September 9, 1994.

[17] *Id.* at 7406, para. 2.

[18] *Id.*

[19] *Id.* at 7414–15, para. 26.

[20] *Id.* at 7426–27, paras. 61–64.

[21] Amendment of Part 36 of The Commission's Rules And Establishment of a Joint Board, CC Docket No. 80–286, FCC 95–282, 36, para. 91 (released July 13, 1995), 60 FR 46803, September 8, 1995.

[22] *Id.* at 10, para. 17.

base high-cost assistance on actual costs reported by LECs.[23] Under the second proposal, assistance would be distributed on the basis of factors related to the cost of providing service rather than on the basis of actual reported costs.[24] The third proposal suggested the distribution of assistance among the States, with State utility commissions deciding the allocation of assistance among the carriers serving the State under distribution plans developed under Commission guidelines and reviewed by the Commission.[25] In addition to the three proposals, comment was solicited on the use of credits, or customer vouchers, directing assistance to LECs selected by the customer.[26] Finally, the Notice invited comment on the abolition, revision, or combination with USF assistance of dial equipment minute (''DEM'') weighting, which currently allows LEC study areas with fewer than 50,000 loops to allocate part of their local switching costs to the interstate jurisdiction.[27]

8. On August 31, we granted requests from interested parties, including the Alaska Public Utilities Commission, for an extension of time for the filing of comments and reply comments, because we were persuaded that an extension would serve the public interest.[28] We noted that an extension would encourage more detailed analysis by interested parties of the complex issues presented in the Notice for their consideration.[29] The new deadlines for filing comments are October 10 and November 9, 1995.[30]

III. Discussion

9. We proposed the interim cap for the purpose of moderating growth in the total level of the USF for the duration of an intended rulemaking that would address possible permanent changes to the USF rules.[31] In imposing the interim cap, we noted that previous changes to the jurisdictional separations rules involved lengthy phase-in periods to ease the transition for affected carriers.[32] Since the intended rulemaking could result in new USF rules retargeting assistance, we concluded that the interim cap would facilitate our ability to implement the new rules in a timely manner.[33]

10. We note that the Commission had limited the duration of the interim cap to two years in the belief that two years would be sufficient for the completion of the rulemaking.[34] We specifically stated that should rulemaking conclude prior to the expiration of the cap, the new rules would replace the interim cap.[35] The issues addressed in this rulemaking are complex, however, and despite diligent effort by the Commission staff and interested parties, it is now clear that their resolution will take more time than the anticipated two years.

11. In view of the progress in the rulemaking process to date, we believe that an additional six months should be sufficient to complete it. Given the scope of the proposals presently under consideration for amending the jurisdictional separations rules,[36] we conclude that the extension of the interim cap for the purpose of continuing to moderate the growth of the USF for the remainder of the rulemaking period is prudent. We propose extending the interim cap for an additional six months while we complete the rulemaking. We seek comment on this proposed extension of the interim rules. We also invite interested parties to propose longer or shorter extensions, with accompanying justifications for the length of time proposed.

IV. Procedural Matters

A. Ex Parte

12. This is a non-restricted notice and comment rulemaking proceeding. ''Ex parte'' presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's rules.[37]

B. Regulatory Flexibility

13. We certify that the Regulatory Flexibility Act of 1980 does not apply to this rulemaking proceeding because if the proposals in this proceeding are adopted, there will not be a significant economic impact on a substantial number of small business entities, as defined by Section 601(3) of the Regulatory Flexibility Act.[38] Because of the nature of local exchange and access service, the Commission has concluded that LECs, including small LECs, are dominant in their fields of operation and therefore are not ''small entities'' as defined by that act.[39] The Secretary shall send a copy of this Notice of Proposed Rulemaking, including the certification, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with Section 603(a) of that act.[40]

C. Comment Dates

14. We invite comment on the proposals and tentative conclusions set forth above. Pursuant to applicable procedures set forth in Sections 1.415 and 1.419 of the Commission's Rules,[41] interested parties may file comments on or before October 18, 1995, and reply comments on or before October 27, 1995. To file formally in this proceeding, you must file an original and four copies of all comments, reply comments, and supporting comments. If you want each Commissioner to receive a personal copy of your comments, you must file an original plus nine copies. You should send comments and reply comments to Office of the Secretary, Federal Communications Commission, Washington, D.C. 20554. Parties should send one copy of any documents filed in this docket to the Commission's copy contractor, International Transcription Service (ITS), 2100 M Street, N.W., Suite 140, Washington, D.C. 20037. We also ask that parties send a copy of their comments to each member of the Federal State Joint Board and its staff, as indicated in the attached service list. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center, Room 239, 1919 M Street, N.W., Washington, D.C. 20554.

V. Ordering Clauses

15. Accordingly, it is ordered that, pursuant to Sections 1, 4(i), 4(j), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. § § 151, 154(i), 154(j), and 403, notice is hereby given of proposed interim amendments to Part 36, Subpart F of the Commission's Rules, 47 C.F.R. Part 36, Subpart F, as described in the Notice of Proposed Rulemaking.

16. It is further ordered, pursuant to Section 410(c) of the Communications Act of 1934, as amended, 47 U.S.C.

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[23] *Id*, at 17, paras. 37–38, at 22, para. 47, at 23–24, para. 51.

[24] *Id*. at 25–31, paras. 56–75.

[25] *Id*. at 32, paras. 76–77.

[26] *Id*. at 10, para. 17.

[27] *Id*. at 7–9, paras. 9–12.

[28] Amendment of Part 36 of the Commission's Rules and Establishment of a Joint Board, Order, CC Docket No. 80–286, DA 95–1876, 2 para. 4 (released September 1, 1995).

[29] *Id*.

[30] *Id*. at 2, para. 5.

[31] Interim Notice, *supra* note 11, at 7114, paras. 1–2.

[32] Interim Order, *supra* note 1, at 305, paras. 17–18.

[33] *Id*. at 305, paras. 16–18.

[34] Interim Notice, *supra* note 11, at 7114, para. 4.

[35] *Id*. at 7114 n. 2; Interim Order, *supra* note 1 at 306, para. 24.

[36] See *supra* para. 7.

[37] See generally 47 CFR 1.1202, 1.1203, 1.1206(a) (1994).

[38] 5 U.S.C. 601(3).

[39] See MTS and WATS Market Structure, 93 FCC 2d 241, 338–39 (1983).

[40] 5 U.S.C. 603(a).

[41] 47 CFR 1.415, 1.419 (1994).

410(c), that the issues relating to interim amendments to Part 36, Subpart F of the Commission's Rules, 47 C.F.R. Part 36, Subpart F, as described in the Notice of Proposed Rulemaking, shall be and hereby are referred to the Federal State Joint Board established in this proceeding for a recommended decision.

List of Subjects in 47 CFR Part 36

Communications commoncarriers; Reporting and recordkeeping requirements; Telephone; Uniform System of Accounts.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

Federal-State Joint Board Service List

The Honorable Sharon L. Nelson, Chairman; Washington Utilities and Transportation Commission; Chandler Plaza Building; 1300 South Evergeen Park Drive, S.W.; Olympia, Washington 98504–7250

The Honorable Cheryl L. Parrino, Chair; Wisconsin Public Service Commission; Post Office Box 7854; Madison, Wisconsin 53707–7854

The Honorable Stephen O. Hewlett, Commissioner; Tennessee Public Service Commission; 460 James Robertson Parkway; Nashville, Tennessee 37243–0505

The Honorable Laska Schoenfelder, Chairman; South Dakota Public Utilities Commission; State Capitol Building; Pierre, South Dakota 57501–5070

The Honorable Reed E. Hundt, Chairman; Federal Communications Commission; 1919 M Street, N.W.—Room 814; Washington, D.C. 20554

The Honorable Andrew C. Barrett, Commissioner; Federal Communications Commission; 1919 M Street, N.W.—Room 826, Stop 0105; Washington, D.C. 20554

The Honorable Susan Ness, Commissioner; Federal Communications Commission; 1919 M Street, N.W.—Room 832; Washington, D.C. 20554

Deborah A. Dupont, FCC Joint Board Staff Chair; Federal Communications Commission; Common Carrier Bureau—Accounting & Audits Div.; 2000 L Street, N.W.—Room 257; Washington, D.C. 20036

Teresa Pitts, State Joint Board Staff Chair; Washington Utilities and Transportation Commission; 1300 South Evergreen Park Drive, S.W.; Olympia, Washington 98504–7250

Charles Bolles; South Dakota Public Utilities Commission; State Capitol Building; Pierre, South Dakota 57501–5070

Elton Calder; Georgia Public Service Commission; 162 State Office Building; 244 Washington Street, S.W.; Atlanta, Georgia 30334

Ronald Choura; Michigan Public Service Commission; 6545 Mercantile Way; Lansing, Michigan 48910

Rowland Curry; Texas Public Utility Commission; 7800 Shoal Creek Blvd.—Suite 400N; Austin, Texas 78757

Ann Dean; Maryland Public Service Commission; 6 St. Paul Centre; Baltimore, Maryland 21202

Dean Evans; California Public Utilities Commission; 505 Van Ness Avenue—Room 4004; San Francisco, California 94102

William Howden; Federal Communications Commission; Common Carrier Bureau—Accounting & Audits Div.; 2000 L Street, N.W.—Room 812; Washington, D.C. 20036

George Johnson; Federal Communications Commission; Common Carrier Bureau—Accounting & Audits Div.; 2000 L Street, N.W.—Room 257; Washington, D.C. 20036

Chris Klein; Tennessee Public Service Commission; 460 James Robertson Parkway; Nashville, Tennessee 37243–0505

Robert Loube; Public Service Commission of District of Columbia; 450 Fifth Street, N.W.; Washington, D.C. 20001

Sam Loudenslager; Arkansas Public Service Commission; 1000 Center Street; Post Office Box C–400; Little Rock, Arkansas 72203

Rafi Mohammed; Federal Communications Commission; Common Carrier Bureau—Accounting and Audits Div.; 2000 L Street—Room 812; Washington, D.C. 20036

Paul Pederson; Missouri Public Service Commission; Post Office Box 360; Jefferson City, Missouri 65102

James Bradford Ramsay; National Association of Regulatory Utility Commissioners; 1102 ICC Building; Constitution Avenue & 12th Street, N.W.; Post Office Box 684; Washington, D.C. 20044

Jonathan Reel; Federal Communications Commission; Common Carrier Bureau—Accounting and Audits Div.; 2000 L Street, N.W.—Room 257; Washington, D.C. 20036

Jeff Richter; Wisconsin Public Service Commission; Post Office Box 7854; Madison, Wisconsin 53707–7854

Gary Seigel; Federal Communications Commission; Common Carrier Bureau—Accounting & Audits Div.; 2000 L. Street, N.W.—Room 812; Washington, D.C. 20036

Joel B. Shifman; Maine Public Utilities Commission; State House Station # 18; Augusta, Maine 04333

Fred Sistarenik; New York Public Service Commission; 3 Empire State Plaza; Albany, New York 12223

Mary Steele; North Carolina Utilities Commission; Box 29510; Raleigh, North Carolina 27626–0510

[FR Doc. 95–25036 Filed 10–5–95; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 61

[CC Docket No. 94–1; FCC 95–406]

Price Cap Performance Review for Local Exchange Carriers

AGENCY: Federal Communications Commission.

ACTION: Further notice of proposed rulemaking.

SUMMARY: On March 30, 1995, the Federal Communications Commission adopted a First Report and Order in this docket, revising its price cap regulations applicable to local exchange carriers (LECs). In that Order, the Commission also stated that it would consider adopting further rule revisions in the near future.

In this Further Notice, the Commission seeks comment on revising its rules governing calculation of the ''X-Factor'' in the price cap index (PCI) formula, and revising the rules governing sharing obligations. The Commission also seeks comment on revising the rules governing the price cap common line formula, and the rules governing treatment of exogenous costs. In a previous further notice of proposed rulemaking, the Commission sought comment on how the price cap rules should be adjusted as the competition faced by local exchange carriers (LECs) develops in the future. The intended effect of this action is to revise the price cap rules to strengthen the existing incentives for LECs to become efficient and innovative.

DATES: Comments must be submitted on or before November 27, 1995. Reply Comments must be submitted on or before December 27, 1995.

ADDRESSES: Tariff Division, Common Carrier Bureau, Room 518, 1919 M Street, NW., Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Steven Spaeth or C. Anthony Bush, Tariff Division, Common Carrier Bureau, (202) 418–1530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Fourth Further Notice adopted September 27, 1995, and released September 27, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours

in the FCC Public Reference Room (Room 230), 1919 M St., N.W., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Suite 140, 2100 M Street, N.W., Washington, D.C. 20037.

Regulatory Flexibility Analysis

We have determined that section 605(b) of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), does not apply to these rules because they do not have a significant economic impact on a substantial number of small entities. The definition of a ''small entity'' in section 3 of the Small Business Act excludes any business that is dominant in its field of operation. Local exchange carriers do not qualify as small entities because they have a nationwide monopoly on ubiquitous access to the subscribers in their service area. The Commission also has found all exchange carriers to be dominant in its competitive carrier proceeding. *See* 85 FCC 2d 1, 23–24 (1980). To the extent that small telephone companies will be affected by these rules, we hereby certify that these rules will not have a significant effect on a substantial number of ''small entities.''

Summary of Report and Order

In this Further Notice, we seek comment on a number of possible rule revisions. The first set of rules we consider revising is related to the calculation of the ''X-Factor.'' The productivity factor, or X-Factor, was included in the LEC price cap plan adopted in 1990 to reflect the fact that productivity growth in the telecommunications industry historically was greater than productivity growth in the economy as a whole. This Further Notice invites comments on three alternative X-Factor calculation methods. The first is Total Factor Productivity (TFP). A TFP method would base the X-Factor on the ratio of an index of total outputs to an index of total inputs. The output index would represent the quantities of goods or services produced, and the input index would represent the quantities of goods or services consumed. The second X-Factor calculation method under consideration is the Historical Revenue Method, which would set the X-Factor at the level necessary to reprice cap LECs' access services so that those LECs would earn a rate of return of 11.25 percent. The third X-Factor calculation method under consideration is the Historical Price Method. This is basically the method used by the Commission to set the X-Factor when it adopted LEC price cap regulation originally in 1990. It would set the X-Factor so that the historical difference between telecommunications price trends and economy-wide price trends will continue in the future.

The Commission invites comment on a number of other X-Factor issues, such as whether the X-Factor should include a consumer productivity dividend. The Commission also seeks comment on the number of X-Factors that should be established in the price cap plan, to reflect the fact that each LEC serves regions with different economic conditions and population densities, and so cannot be reasonably expected to achieve the same level of productivity growth. In addition, this Further Notice solicits comment on whether the Commission should adopt X-Factors that would remain fixed until the next scheduled performance review, as the Commission did in the initial price cap plan. Alternatively, the Commission could adopt X-Factors based on a moving average of past productivity measures, which would be updated on a periodic basis, such as in the annual access tariff filings.

The Commission also seeks comment on whether the sharing mechanism can be eliminated. In the *First Report and Order* in this Docket, 60 FR 19526, Apr. 19, 1995, the Commission found that the sharing requirement blunts the efficiency incentives otherwise created by the price cap plan. Therefore, the Commission tentatively concluded that one of the X-Factors in the long-term price cap plan should have no sharing obligations, and established a goal in the *First Report and Order* to eliminate sharing eventually. Sharing serves three beneficial functions, however: (1) A ''backstop'' mechanism, in case the X-Factor was substantially in error, or in case a particular LEC's productivity varied substantially from the average; (2) a ''flow-through'' mechanism, to flow through to customers gains made by carriers in reducing their unit costs in excess of specified levels, as measured by interstate earnings; and (3) a ''matching'' mechanism, to encourage LECs to choose the X-Factor that most closely matches their actual rate of productivity growth. This Further Notice seeks comment on the extent to which the Commission can establish other mechanisms to replace the functions served by sharing. Specifically, the Commission seeks comment on whether a moving average X-Factor, together with multiple X-Factors, could replace the backstop function and the flow-through function of sharing. To replace the matching function, the Commission could develop a mechanism to assign an appropriate X-Factor to each LEC. Alternatively, the Commission could permit additional pricing flexibility to LECs electing higher X-Factors.

Finally, the Commission seeks comment on a number of related issues. First, based on the method of calculation of the X-Factor, can the Commission eliminate the separate price cap formula for the common line basket? Second, based on the method of calculation of the X-Factor, would it still be necessary for the Commission to treat some costs as exogenous?

Ordering Clauses

Accordingly, it is ordered that notice is hereby given of the rulemaking described above and that comment is sought on these issues.

It is further ordered that pursuant to applicable procedures set forth in § 1.399 and 1.411 *et seq.* of the Commission's rules, 47 CFR 1.399, 1.411 *et seq.*, comments shall be filed with the Secretary, Federal Communications Commission, Washington, D.C. 20554 no later than November 27, 1995. Reply comments shall be filed no later than December 27, 1995. To file formally in this proceeding, participants must file an original and four copies of all comments, reply comments, and supporting comments. If participants want each Commissioner to receive a personal copy of their comments, an original plus nine copies must be filed. In addition, parties should file two copies of any such pleading with the Tariff Division, Common Carrier Bureau, Room 518, 1919 M Street, NW., Washington, DC 20554, and one copy of any pleadings should be submitted on computer disk to the Industry Analysis Division, Common Carrier Bureau, Room 534, 1919 M Street, NW., Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center, Room 239, 1919 M Street, NW., Washington, DC 20554.

List of Subjects in 47 CFR Part 61

Communications common carriers, Tariffs.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95–24882 Filed 10–5–95; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 61

[CC Docket No. 94–1; FCC 95–394]

Price Cap Performance Review for Local Exchange Carriers; Treatment of Video Dialtone Services Under Price Cap Regulation

AGENCY: Federal Communications Commission.

ACTION: Further notice of proposed rulemaking.

SUMMARY: On October 20, 1994, the Commission adopted a Memorandum Opinion and Order concluding that the basic video dialtone offerings of local exchange carriers (LECs) would be subject to the existing price cap rules. In the order, the Commission stated it would initiate a rulemaking proceeding on whether to create a separate price cap basket for LEC video dialtone service. On February 7, 1995 the Commission issued a notice of proposed rulemaking in this docket seeking comment on whether to establish a separate price cap basket for LEC video dialtone service. In a companion order adopted today the Commission established a separate price cap basket for video dialtone and required LECs to segregate video dialtone costs and revenues from those for telephony service for purposes of sharing and the low-end adjustment once LEC provision of video dialtone exceeds a *de minimis* threshold. In the Order, the Commission also declined to establish sharing and low end-adjustments for the video dialtone basket for LECs exceeding the threshold. The Order initiated this Further Notice to obtain comment on the specific level for the *de minimis* threshold as well as on the procedures for allocating costs to the video dialtone basket for purposes of sharing and the low-end adjustment once a LEC has exceeded the threshold.

DATES: Comments must be submitted on or before October 27, 1995. Reply Comments must be submitted on or before November 17, 1995.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Claudia Pabo, Policy and Program Planning Division, Common Carrier Bureau, (202) 418–1595, or Cheryl Lynn Schneider, Tariff Division, Common Carrier Bureau, (202) 418–1530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Third Further Notice of Proposed Rulemaking adopted September 14, 1995, and released September 21, 1995. The full text of the Commission's decision is available for public inspection and copying during normal business hours in the FCC Public Reference Room (Room 230), 1919 M St., NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Suite 140, 2100 M Street, NW., Washington, DC 20037.

Regulatory Flexibility Analysis

We have determined that section 605(b) of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), does not apply to these proposed rules because they do not have a significant economic impact on a substantial number of small entities, as defined by section 301(3) of the Regulatory Flexibility Act. Carriers subject to price cap regulation for local exchange access services affected by the rule amendments adopted in this Order generally are large corporations or affiliates of such corporations.

Summary of Further Notice of Proposed Rulemaking

Having concluded that video dialtone costs and revenues should be segregated from those for telephony service for purposes of sharing and the low-end adjustment once LEC provision of video dialtone exceeds a *de minimis* threshold, we seek comment on the following proposals and invite parties to suggest alternate sources for the threshold data, and different procedures for setting the threshold. We also invite interested parties to suggest alternative methods for allocating costs to the video dialtone basket once the LEC exceeded the threshold.

We propose basing the *de minimis* threshold on the data carriers are currently required to submit under Responsible Accounting Officer (RAO) Letter 25. In RAO Letter 25, the Accounting and Audits Division of the Common Carrier Bureau required LECs to maintain subsidiary records by USOA accounts for all wholly dedicated and shared investments, expense and revenue related to providing video dialtone service. Using the RAO Letter 25 data, the threshold could be set at the amount of dedicated video dialtone investment that would reduce the LEC overall rate of return by a specified amount, such 10 or 25 basis points, for example.

We also need to specify a method or factor to be used in Part 69 for allocating video dialtone costs to the video dialtone basket for purposes of sharing and the low-end adjustment once the threshold has been passed in the case of LECs that select an X-Factor with sharing and a low end adjustment for telephony. We could allocate costs to the video dialtone basket using the approach in the new services test applied in the tariff review process for setting video dialtone rates. Under this approach, if somewhat different cost allocation methodologies are used for a single LEC due, for example, to differences in technology for various video dialtone systems, we propose to weight the application of the different cost allocation methodologies in some manner. For example, use of the different cost allocation methodologies could be weighted based on video dialtone investment for the relevant systems. As an alternative to use of the new services costs allocation methodology, we seek comment on whether we should adopt a fixed cost allocation factor, such as a specified percentage, and, if so, what level of allocator we should use. Parties advocating the use of a fixed allocator should explain the basis for their proposal and the public interest goals that would be advanced by use of such an allocator. We also ask interested parties to address the implications of allocating costs to the video dialtone basket on a basis different than that used to set video dialtone rates.

Ordering Clauses

It is ordered that, pursuant to sections 1, 4, 201–205, 215, and 218 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, 201–205, 215, 218, a third further notice of proposed rulemaking is hereby adopted and that comment is sought on the issues contained therein. Interested parties may file comments on or before October 27, 1995, and reply comments on or before November 17, 1995.

It is further ordered that to file formally in this proceeding, parties must file an original and four copies of all comments, reply comments, and supporting comments. If parties want each Commissioner to receive a personal copy of their comments, parties must file an original plus nine copies. Comments and reply comments should be sent to the Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Parties should also file one copy of any documents filed in this docket with the Commission's copy contractor, International Transcription Service, Inc., Room 246, 1919 M Street, NW., Washington, DC 20037. Parties should also send one copy of any documents filed in this proceeding to Ms. Janice Myles, Policy and Program Planning Division, Common Carrier Bureau, Room 544, 1919 M Street NW., Washington, DC 20554. Comments and

reply comments will be available for public inspection during regular business hours in the FCC Reference Center, Room 239, 1919 M Street, NW., Washington, DC 20554.

List of Subjects in 47 CFR Part 61

Communications common carriers, Reporting and recordkeeping requirements.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95–24883 Filed 10–5–95; 8:45 am]

BILLING CODE 6712–01–M

Notices

Federal Register
Vol. 60, No. 194
Friday, October 6, 1995

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

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Opportunity to Comment on the Applicant for the Grand Forks (ND) Area

AGENCY: Grain Inspection, Packers and Stockyards Administration (GIPSA).

ACTION: Notice.

SUMMARY: GIPSA request comments on the applicant for designation to provide official services in the geographic area currently assigned to Grand Forks Grain Inspection, Inc. (Grand Forks).

DATES: Comments must be postmarked, or sent by telecopier (FAX) or electronic mail by November 2, 1995.

ADDRESSES: Comments must be submitted in writing to Janet M. Hart, Chief, Review Branch, Compliance Division, GIPSA, USDA, Room 1647 South Building, P.O. Box 96454, Washington, DC 20090–6454. SprintMail users may respond to [A:ATTMAIL,O:USDA,ID:A36JHART]. ATTMAIL and FTS2000MAIL users may respond to !A36JHART. Telecopier (FAX) users may send comments to the automatic telecopier machine at 202–690–2755, attention: Janet M. Hart. All comments received will be made available for public inspection at the above address located at 1400 Independence Avenue, S.W., during regular business hours.

FOR FURTHER INFORMATION CONTACT: Janet M. Hart, telephone 202–720–8525.

SUPPLEMENTARY INFORMATION:

This action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12866 and Departmental Regulation 1512–1; therefore, the Executive Order and Departmental Regulation do not apply to this action.

In the September 5, 1995, Federal Register (60 FR 46108), GIPSA asked persons interested in providing official services in the geographic area assigned to Grand Forks to submit an application for designation. Grand Forks Grain Inspection Department, Inc., the only applicant, applied for designation to provide official services in the entire available area.

GIPSA is publishing this notice to provide interested persons the opportunity to present comments concerning the applicant. Commenters are encouraged to submit reasons and pertinent data for support or objection to the designation of this applicant. All comments must be submitted to the Compliance Division at the above address. Comments and other available information will be considered in making a final decision. GIPSA will publish notice of the final decision in the Federal Register, and GIPSA will send the applicants written notification of the decision.

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

Dated: September 29, 1995

Neil E. Porter

Director, Compliance Division

[FR Doc. 95–24862 Filed 10–5–95; 8:45 am]

BILLING CODE 3410–EN–F

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–820]

Ferrosilicon From Brazil; Termination In-Part of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of termination in-part of antidumping duty administrative review.

SUMMARY: On April 14, 1995, the Department of Commerce (the Department) initiated an administrative review of the antidumping duty order on ferrosilicon from Brazil. The Department is now terminating this review in-part with respect to Companhia Ferroligas Minas Gerais-Minasligas (Minasligas) and Companhia Brasileira Carbureto de Calcio (CBCC).

EFFECTIVE DATE: October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Arthur N. DuBois or Thomas Futtner, Office of Antidumping Compliance, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, D.C. 20230, telephone (202) 482–6312/3814.

SUPPLEMENTARY INFORMATION:

Background

On April 14, 1995 (60 FR 19017), and on May 15, 1995 (60 FR 25886), the Department published in the Federal Register notices of initiation of administrative review of the antidumping duty order on ferrosilicon from Brazil. These notices stated that the Department would review merchandise sold in the United States by Minasligas, CBCC, and Companhia de Ferroligas da Bahia (Ferbasa) during the period March 1, 1994 through February 28, 1995. The correct period is August 16, 1993 through February 28, 1995.

The petitioners in this case withdrew their request for review of Minasligas and CBCC on July 13, 1995. Under CFR 353.22(a)(5) (1994), a party requesting a review may withdraw that request no later than 90 days after the date of publication on the notice of initiation. Because the withdrawal occurred within the time frame specified in 19 CFR 353.22(a)(5), and no other interested party has requested an administrative review for Minasligas or for CBCC for this period, the Department is now terminating this review in-part for Minasligas and CBCC. The review of Ferbasa will continue.

This notice is published pursuant to 19 CFR 353.22(a)(5).

Dated: September 28, 1995.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 95–24924 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DS–P

[A–588–814]

Polyethylene Terephthalate Film, Sheet, and Strip From Japan; Initiation and Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review, and Intent To Revoke Order

September 29, 1995.

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Initiation and Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review, and Intent To Revoke Order.

SUMMARY: On June 5, 1991, the Department of Commerce (the Department) published an antidumping duty order on polyethylene terephthalate film, sheet, and strip from Japan. On July 7, 1995, E.I. Du Pont de Nemours & Company, Hoechst Celanese Corporation and ICI American Inc. (together, the petitioners) in this proceeding, submitted a request for a changed circumstances administrative review and revocation of the order on the basis that the order no longer is of interest to the petitioners. On July 21, 1993; July 15, 1994; and July 14, 1995, the Department initiated administrative reviews of the antidumping order on polyethylene terephthalate film, sheet, and strip from Japan, covering the periods: June 1, 1992 through May 31, 1993; June 1, 1993 through May 31, 1994; and June 1, 1994 through May 31, 1995, respectively. We are now revoking the order, based on the fact that this order is no longer of interest to domestic parties; accordingly we are also terminating the above-mentioned administrative reviews.

EFFECTIVE DATE: October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Arthur N. DuBois or Thomas Futtner, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, D.C. 20230; telephone: (202) 482–6312/3814.

SUPPLEMENTARY INFORMATION:

Background

On June 5, 1991, the Department published in the Federal Register an antidumping duty order on polyethylene terephthalate film, sheet, and strip from Japan. (*Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip from Japan*, 56 FR 25669, June 5, 1991).

On June 30, 1993, one respondent, Toray, requested an administrative review and one U.S. producer, Toray Plastics America (TPA), requested an administrative review for two other Japanese manufacturers/exporters of PET film, Teijin and Diafoil. We initiated the review, covering entries from June 1, 1992 through May 31, 1993, on July 21, 1993 (*Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 58 FR 39007, July 21, 1993).

On June 30, 1994, the petitioners, one repondent, and one U.S. producer, TPA, requested an administrative review of three Japanese manufacturers/exporters of PET film, Toray, Teijin, and Magphane. We initiated a review of these three firms covering entries in the period June 1, 1993 through May 31, 1994, on July 15, 1994 (*Initiation of Antidumping Duty Administrative Reviews and Requests for Revocation in Part*, 59 FR 36160, July 15, 1994).

On June 30, 1995, one respondent, Toray, requested an administrative review. We initiated a review of Toray covering entries in the period June 1, 1994 through May 31, 1995 on July 14, 1995. (*Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part*, 60 FR 36260, July 14, 1995).

On July 7, 1995, E.I. Du Pont de Nemours & Company, Hoechst Celanese Corporation and ICI American Inc. (together, the petitioners) in this proceeding, submitted a request for a changed circumstances administrative review and revocation of the order on the basis that the order no longer is of interest to the petitioners.

In accordance with 19 CFR 353.25(d)(2) the Department found that petitioners affirmative statement of no interest was a reasonable basis to believe that the requirements for revocation based on changed circumstances were met. Therefore, pursuant to 19 CFR 353.25(d)(2) and 353.22(f)(1), on August 18, 1995, the Department published in the Federal Register a notice of initiation and preliminary results of changed circumstances to determine whether to revoke the order with an effective date of June 1, 1992. (*Polyethylene Terephthalate Film, Sheet, and Strip from Japan; Initiation and Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review, and Intent to Revoke Order*, 60 FR 43119, August 18, 1995). We gave interested parties an opportunity to comment on the preliminary results of this changed circumstances review. We received no comments.

Scope of the Review

Imports covered by the review are shipments of all gauges of raw, pretreated, or primed PET film, sheet, and strip, whether extruded or coextruded. The films excluded from the scope of this order are metallized films and other finished films that have had a least one of their surfaces modified by the application of performance-enhancing resin or inorganic layer more than 0.00001 inches (0.254 micrometers) thick. Roller transport cleaning film which has at least one of its surfaces modified by the application of 0.5 micrometers of SBR latex has also been ruled as not within the scope of the order.

PET film from Japan is currently classifiable under Harmonized Tariff Schedule (HTS) item number 3920.62.0000. The HTS item numbers are provided for convenience and for Customs purposes only. The written descriptions remain dispositive.

This changed circumstance administrative review covers all manufacturers/exporters of pet film from Japan.

Final Results of Changed Circumstances Review; Revocation of Antidumping Duty Order; Termination of Antidumping Duty Administrative Reviews

Since the antidumping order on PET film is no longer of interest to the interested parties, as defined in paragraphs (k)(3), (k)(4), (k)(5), and (k)(6) of section 353.2, the Department concludes that the requirements for revocation based on changed circumstances are met.

Therefore, the Department is revoking the order on polyethylene terephthalate film, sheet, and strip from Japan in accordance with sections 751 (b) and (c) of the Tariff Act of 1930 (the Act), and 19 CFR 353.25(d)(1). This revocation applies to all entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after June 1, 1992. Accordingly, the Departments is also terminating the reviews covering entries made in the following periods: June 1, 1992 through May 31, 1993; June 1, 1993 through May 31, 1994; and June 1, 1994 through May 31, 1995.

The Department will instruct the Customs Service to proceed with liquidation, without regard to antidumping duties, of all unliquidated entries of subject merchandise entered or withdrawn from wearehouse, for consumption on or after June 1, 1992. The Department will further instruct the Customs Service to refund with interest any estimated duties collected with respect to unliquidated entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after June 1, 1992, in accordance with section 778 of the Act.

This changed circumstances review, revocation of the antidumping duty order, termination of second, third and fourth reviews, and notice are in accordance wtih sections 751 (b) and (c) of the Act (19 U.S.C. 1675 (b) and (c)) and sections 353.22(f) and 353.25(d) of the Department's regulations.

Dated: September 29, 1995.

Paul L. Joffe,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 95–24923 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–25–P

[A–834–802, A–835–802, A–844–802]

Notice of Price Determination; Uranium From Kazakhstan, Kyrgyzstan, and Uzbekistan

AGENCY: International Trade Administration, Import Administration, Commerce.

ACTION: Notice of Price Dermination; Uranium from Kazakhstan, Kyrgyzstan, and Uzbekistan.

SUMMARY: Pursuant to section IV.C.1. of the antidumping suspension agreements on uranium from Kazakhstan, Kyrgyzstan, and Uzbekistan, the Department calculated a price for uranium of $12.25/lb. On the basis of this price, the export quota for uranium pursuant to Section IV.A. of the Uzbek and Kyrgyz agreements is zero. The export quota for uranium pursuant to Section IV.A. of the Kazakhstani agreement, as amended on March 27, 1995, is 500,000 lbs. for the period October 1, 1995, through March 31, 1996. Exports pursuant to other provisions of the agreements are not affected by this price.

EFFECTIVE DATE: October 2, 1995.

FOR FURTHER INFORMATION CONTACT: James Doyle or Daniel Miller, Office of Agreements Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Ave., NW, Washington, DC 20230; telephone: (202) 482–0172 or (202) 482–1102, respectively.

Price Calculation

Background

Section IV.C.1. of each agreement specifies that the Department of Commerce (DOC) will issue its observed market price on October 1, 1995, and use it to determine the quota applicable to exports from the various republics during the period October 1, 1995 to March 31, 1996. Consistent with the Department's letters of interpretation dated February 22, 1993, we provided interested parties our preliminary price determination on September 15, 1995.

Calculation Summary

Section IV.C.1. of each agreement specifies how the components of the market price are reached. In order to determine the spot market price, the Department utilized the monthly average of the Uranium Price Information System Spot Price Indicator (UPIS SPI) and the weekly average of the Uranium Exchange Spot Price (Ux Spot). In order to determine the long-term market price, the Department utilized the weighted average long-term price as determined by the Department on the basis of information provided by market participants and a simple average of the UPIS Base Price for the months in which there were new contracts reported.

Our letters to market participants provided a contract summary sheet and directions requesting the submitter to report his/her best estimate of the future price of merchandise to be delivered in accordance with the contract delivery schedules (in U.S. dollars per pound U_3O_8 equivalent). Using the information reported in the proprietary summary sheets, the Department calculated the present value of the prices reported for any future deliveries assuming an annual inflation rate of 2.65 percent, which was derived from a rolling average of the annual GNP Implicit Price Deflator index from the past four years. The Department used the base quantities reported on the summary sheet for the purpose of weight-averaging the prices of the long-term contracts submitted by market participants. We then calculated a simple average of the UPIS Base Price and the long-term price determined by the Department.

Weighting

The Department used the average spot and long-term volumes of U.S. utility and domestic supplier purchases, as reported by the Energy Information Administration (EIA), to weight the spot and long-term components of the observed price. In this instance, we have used purchase data from the period 1989–1992, as in the previous determination. During this period, the spot market accounted for 31.39 percent of total purchases, and the long-term market for 68.61 percent. We were not able to include data from the 1993 and 1994 EIA Uranium Industry Annuals because it has been withheld due to its proprietary nature.

Calculation Announcement

The Department determined, using the methodology and information described above, that the observed market price is $12.25. This reflects an average spot market price of $11.60, weighted at 31.39 percent, and an average long-term contract price of $12.54, weighted at 68.61 percent. Since this price is below the $13.00/lb. minimum expressed in Appendix A of the Uzbek and Kyrgyz agreements, there will be no quota under Section IV.A. of the agreements available to these republics for the period October 1, 1995 to March 31, 1996. However, since this price is above the $12.00/lb. minimum expressed in Appendix A of the amended Kazakhstani agreement, Kazakhstan receives a quota of 500,000 lbs. for the period October 1, 1995 to March 31, 1996. We have determined that the observed market price for uranium is $12.25/lb. The Department invites parties to provide pricing information for use in the next price determination. Any such information should be provided for the record and should be submitted to the Department by March 5, 1996.

Dated: October 2, 1995.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 95–24925 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DS–P

[A–588–815]

Gray Portland Cement and Clinker From Japan; Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Preliminary Results of Antidumping Duty Administrative Review.

SUMMARY: In response to a request from the Ad Hoc Committee of Southern California Producers of Gray Portland Cement (the petitioner) and Onoda Cement Company, Ltd. (the respondent), the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on gray portland cement and clinker from Japan. The review covers one manufacturer/exporter, Onoda Cement Co., Ltd. (Onoda), and the period May 1, 1993, through April 30, 1994 (POR). The review indicates the existence of dumping margins during this period.

We have preliminarily determined that sales have been made below the foreign market value (FMV). If these preliminary results are adopted in our final results of administrative review, we will instruct the U.S. Customs Service (Customs) to assess antidumping duties equal to the difference between the United States price (USP) and FMV. Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Amy S. Wei or Zev Primor, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone (202) 482–5253.

SUPPLEMENTARY INFORMATION:

Background

On May 4, 1994, the Department published a notice of ''Opportunity to Request an Administrative Review'' (59 FR 23051) of the antidumping duty order on gray portland cement and clinker from Japan (56 FR 21658, May 10, 1991). On May 12, 1994, and May 31, 1994, requests were submitted by the respondent and petitioner, respectively, for the Department to conduct an administrative review of the antidumping duty order on gray portland cement and clinker from Japan for Onoda. We initiated the review, covering the period May 1, 1993, through April 30, 1994, on June 15, 1994 (59 FR 30770). The Department is conducting this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Review

The products covered by this review are gray portland cement and clinker from Japan. Gray portland cement is a hydraulic cement and the primary component of concrete. Clinker, an intermediate material produced when manufacturing cement, has no use other than grinding into finished cement. Microfine cement was specifically excluded from the antidumping duty order. Gray portland cement is currently classifiable under the Harmonized Tariff Schedule (HTS) item number 2523.29, and clinker is currently classifiable under HTS item number 2523.10. Gray portland cement has also been entered under item number 2523.90 as ''other hydraulic cements''.

The HTS item numbers are provided for convenience and Customs purposes. The written product description remains dispositive as to the scope of the product coverage.

This review covers Onoda and the period May 1, 1993 through April 30, 1994.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the Department's regulations are references to the provisions as they existed on December 31, 1994.

Product Comparisons

Product comparisons were made on the basis of standards established by the American Society for Testing and Materials (ASTM standards). All of the cement sold in the United States fell within one ASTM standard, Type I. Onoda provided documents indicating the chemical composition, technical specifications, and uses for each cement type sold in the home market during the period of review.

Based on information submitted on the record and our findings at verification, we have determined that Type N cement, which is sold in the home market, is the closest comparable model to Type I cement, given the similar general chemical compositions and uses.

Onoda made no sales of clinker in the United States during the period of review.

Use of Best Information Available

At verification, we were unable to substantiate Onoda's short-term interest rates. As a result, in accordance with section 776(c) of the Act, we are using best information available (BIA) for Onoda's home market credit expense. As BIA, we used the lowest short-term interest rate reported by Onoda in its questionnaire response for the POR. We multiplied this rate by the number of days between the dates of payment and shipment and divided by 365 days for each home market sale. This amount was then multiplied by the gross unit price reported for each sale in order to calculate credit expense.

United States Price

In calculating USP, the Department used purchase price sales, as defined in section 772(b) of the Act. We made adjustments, where appropriate, for loading costs, ocean freight, marine insurance, customs user fees and harbor fees, interest revenue, credit, and document handling fees. The Department also made an adjustment to the amount of taxes included in USP in accordance with the Department's tax adjustment methodology (*see Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Silicomanganese from Venezuela,* 59 FR 31204, June 17, 1994).

Foreign Market Value

In calculating FMV, we used home market price, as defined in section 773(a) of the Act. Home market price was based on FOB, CIF terminal, pick-up, or delivered prices to related and unrelated customers in the home market. We did not include those home market sales to those related parties which were not made at arm's length prices. In order to determine whether these sales were made at arm's-length prices, we calculated a weighted-average price of all of Onoda's sales to unrelated customers. We compared this price to a weighted-average price of the home market sales for each related party. Where the weighted-average price charged to a related party was less than the weighted-average price charged to all of Onoda's unrelated customers, we determined that those related party sales were not made at arm's-length prices, and removed those sales from our FMV calculation.

Due to the existence of sales below the cost of production (COP) in a previous administrative review, the Department had reasonable grounds to believe or suspect that sales below the COP may have occurred during this review, as explained in section 773(b)(2)(A)(ii) of the Act. Therefore, in accordance with section 773(b)(1) of the Act, the Department initiated a COP investigation for this review. We calculated COP based on Onoda's reported cost of manufacturing, selling expenses, general and administrative expenses, and net interest expense, as defined in 19 CFR 353.51(c). We compared COP to home market prices, net of movement charges, price adjustments, and discounts.

The results of our cost test indicated that more than 10 percent but less than 90 percent of home market sales were below the COP, indicating that the below-cost sales were made in substantial quantities. In addition, we determined that the below-cost sales were made over an extended period of time, since these sales occurred in more than two months of the review period. Furthermore, no evidence was presented to indicate that below-cost COP prices would permit the recovery of all costs within a reasonable period of time in the normal course of trade. Thus, we dropped from our calculation of FMV all home market sales that were made below the COP.

Using the remaining sales for calculating the FMV used in the dumping calculation, we made adjustments, where appropriate, for credit, interest revenue, packing, post-sale freight costs, and all rebates and discounts. The Department also made an adjustment to the amount of consumption taxes included in FMV in accordance with the Department's aforementioned tax adjustment methodology. In accordance with 19 CFR 353.56(b)(1), we offset commissions paid in the home market with indirect selling expenses from the U.S. market

since no sales commissions were paid in the U.S. market. In addition, Onoda was unable to provide dates of payment for some home market sales, since Onoda claimed that it had not received payment for these sales by the time the home market sales tape was created. As a result, we have calculated the weighted-average number of days between the dates of shipment and the dates of payment for those home market sales where the dates of payment were reported. We added this weighted-average number of days to the shipment dates of those home market sales with missing dates of payment. We then used these dates as the dates of payment for these sales.

The Department did not deduct pre-sale transportation costs, in accordance with the United States Court of Appeals for the Federal Circuit's ruling in *The Ad Hoc Committee of AZ–NM–TX–FL Producers of Gray Portland Cement* v. *United States,* 13 F.3d 398 (Fed. Cir. 1994). This decision allows us to deduct pre-sale transportation costs from FMV only if these expenses are directly related to the home market sales, in accordance with 19 CFR 353.56(a). In order to determine whether pre-sale transportation costs are direct, the Department examines pre-sale warehousing expenses, since the pre-sale transportation costs incurred in positioning the merchandise at the warehouse are, for analytical purposes, inextricably linked to the pre-sale warehousing expenses. Since Onoda reported that it incurred no after-sale warehousing expenses and did not claim any warehousing expenses as direct circumstance-of-sale adjustments in its questionnaire responses, we determined that Onoda's warehousing expenses were pre-sale, indirect selling expenses. Then, in the absence of contrary evidence, pre-sale transportation costs were also treated as indirect expenses (see *Gray Portland Cement and Clinker From Japan; Final Results of Antidumping Duty Administrative Review,* 60 FR 43761, 43766, Comment 9, August 23, 1995).

Where appropriate, we made further adjustments to FMV to account for differences in physical characteristics of the merchandise, in accordance with 19 CFR 353.57 of the Department's regulations.

Preliminary Results of Review

As a result of our comparison of USP to FMV, the Department preliminarily determines that a margin of 28.32 percent exists for Onoda for the period May 1, 1993, through April 30, 1994.

Parties to the proceeding may request disclosure within 5 days of the date of publication of this notice and any interested party may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the date of publication of this notice, or the first workday thereafter and will be limited to those issues raised in the case briefs and/or written comment. Case briefs and/or written comments from interested parties may be submitted not later than 30 days after the date of publication. Rebuttal briefs and rebuttals to written comments, limited to the issues raised in the case briefs and comments, may be filed not later than 37 days after the date of publication. The Department will publish the final results of this administrative review, including the results of its analysis of any written comments or case briefs.

The Department shall determine, and Customs shall assess, antidumping duties on all appropriate entries. Individual differences between USP and FMV may vary from the percentage stated above. The Department will issue appraisement instructions directly to the Customs.

Furthermore, the following deposit requirements will be effective for all shipments of the subject merchandise, entered or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(1) of the Act: (1) the cash deposit rate for Onoda will be the rate established in the final results of this administrative review; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a previous review or the original less-than-fair-value (LTFV) investigation, the cash deposit rate will continue to be the rate published in the most recent final results or determination for which the manufacturer or exporter received a company-specific rate; (3) if the exporter is not a firm covered in this review, earlier reviews, or the original investigation, but the manufacturer is, the cash deposit rate will be that established for the manufacturer of the merchandise in these final results of review, earlier reviews, or the original investigation, whichever is the most recent; and (4) the ''all others'' rate will be 70.23 percent, as specified in the final results of redetermination pursuant to court remand (60 FR 24832, May 10, 1995).

These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a preliminary reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22.

Dated: September 27, 1995.

Paul L. Joffe,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 95–24926 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DS–P

[A–412–817]

Initiation of Antidumping Duty Investigation: Foam Extruded PVC and Polystyrene Framing Stock From the United Kingdom

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Ellen Grebasch at (202) 482–3773, Dorothy Tomaszewski at (202) 482–0631 or Erik Warga at (202) 482–0922, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, DC 20230.

INITIATION OF INVESTIGATIONS:

The Applicable Statute

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA).

The Petition

On September 8, 1995, the Department of Commerce (the Department) received a petition filed in proper form by Marley Mouldings, Inc. (the petitioner), a producer of foam extruded polyvinyl chloride (PVC) and polystyrene framing stock. A supplement to the petition was filed on September 22, 1995.

In accordance with section 732(b) of the Act, the petitioner alleges that imports of foam extruded PVC and polystyrene framing stock from the United Kingdom are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, a U.S. industry.

The petitioner states that they have standing to file the petition because they are interested parties, as defined under section 771(9)(C) of the Act.

Determination of Industry Support for the Petition

Section 732(c)(4)(A) of the Act requires the Department to determine, prior to the initiation of an investigation, that a minimum percentage of the domestic industry supports an antidumping petition. A petition meets these minimum requirements if (1) the domestic producers or workers who support the petition account for at least 25 percent of the total production of the domestic like product; and (2) the domestic producers or workers who support the petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition.

A review of the production data provided in the petition and other information readily available to the Department indicates that the petitioner accounts for more than 25 percent of the total production of the domestic like product and for more than 50 percent of that produced by companies expressing support for, or opposition to, the petition. The Department received no expressions of opposition to the petition from any interested party. Accordingly, the Department determines that the petition is supported by the domestic industry.

Scope of the Investigations

For purposes of these investigations, all extruded PVC and polystyrene framing stock regardless of color, finish, width or length. Finished frames assembled from foam extruded PVC and polystyrene framing stock are excluded. The merchandise under investigation is currently classifiable under HTS subheadings 3924.90.20.00; 3926.90.90.90; 3926.90.95.90; and 3926.90.98.90. Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of these investigations is dispositive.

Export Price and Normal Value

Export price was based on a price list from a U.K. producer with the terms of sale on delivered basis. The petitioner made adjustments to the export prices for foreign inland freight, handling, ocean freight, marine insurance, U.S. brokerage, U.S. duties, and U.S. inland freight.

Normal value was based on the same price list, also with the terms of sale on a delivered basis. The petitioner made adjustments to the normal value for foreign inland freight.

Based on comparisons of export price to normal value, the calculated dumping margins for foam extruded PVC and polystyrene framing stock from the United Kingdom range from 20.82 percent to 48.96 percent.

Fair Value Comparisons

Based on the data provided by the petitioner, there is reason to believe that imports of foam extruded PVC and polystyrene framing stock from the United Kingdom are being, or likely to be, sold at less than fair value.

Initiation of Investigations

We have examined the petition on foam extruded PVC and polystyrene framing stock and have found that it meets the requirements of section 732 of the Act, including the requirements concerning allegations of the material injury or threat of material injury to the domestic producers of a domestic like product by reason of the complained-of imports, allegedly sold at less than fair value. Therefore, we are initiating an antidumping duty investigation to determine whether imports of foam extruded PVC and polystyrene framing stock from the United Kingdom are being, or are likely to be, sold in the United States at less than fair value. Unless extended, we will make our preliminary determination by February 15, 1996.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act, copies of the public versions of the petition have been provided to the representatives of the government of the United Kingdom. We will attempt to provide copies of the public versions of the petition to all the exporters named in the petition.

International Trade Commission (ITC) Notification

We have notified the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determination by the ITC

The ITC will determine by October 23, 1995, whether there is a reasonable indication that imports of foam extruded PVC and polystyrene framing stock from the United Kingdom are causing material injury, or threatening to cause material injury, to a U.S. industry. A negative ITC determination will result in the investigation being terminated; otherwise, the investigation will proceed according to statutory and regulatory time limits.

This notice is published pursuant to section 732(c)(2) of the Act.

Dated: September 28, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–24928 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DS–P

[C–549–802]

Ball Bearings and Parts Thereof From Thailand; Final Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Final Results of Countervailing Duty Administrative Review.

SUMMARY: On May 8, 1995, the Department of Commerce (the Department) published in the Federal Register its preliminary results of administrative review of the countervailing duty order on *Ball Bearings and Parts Thereof from Thailand* for the period January 1, 1992 through December 31, 1992. We have completed this review and determine the net subsidy to be 4.29 percent *ad valorem* for all companies. We will instruct the U.S. Customs Service to assess countervailing duties as indicated above.

EFFECTIVE DATE: October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Robert Copyak or Kelly Parkhill, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution

Avenue, NW., Washington, DC 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On May 8, 1995, the Department published in the Federal Register (60 FR 22563) the preliminary results of its administrative review of the countervailing duty order on *Ball Bearings and Parts Thereof from Thailand*. The Department has now completed this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

We invited interested parties to comment on the preliminary results. On June 7, 1995, a case brief was submitted by Pelmec Thai Ltd., NMB Thai Ltd., and NMB Hi-Tech Ltd. (three related companies, hereinafter the Minebea Group), producers/exporters of the subject merchandise during the review period (respondents). On June 14, 1995, a rebuttal brief was submitted by the Torrington Company (petitioner). The review covers the period January 1, 1992 through December 31, 1992. The review involves the Minebea Group of companies, which accounts for virtually all exports of subject merchandise from Thailand, and nine programs.

Applicable Statute and Regulations

The Department is conducting this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994. However, references to the Department's *Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments*, 54 FR 23366 (May 31, 1989) (*Proposed Regulations*), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the *Proposed Regulations* were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the Uruguay Round Agreements Act. *See* 60 FR 80 (Jan. 3, 1995).

Scope of the Review

Imports covered by this review are ball bearings and parts thereof. Such merchandise is described in detail in Appendix A to this notice. The *Harmonized Tariff Schedule* (HTS) item numbers listed in Appendix A are provided for convenience and Customs purposes. The written description remains dispositive.

Calculation Methodology for Assessment and Cash Deposit Purposes

In the first administrative review, respondents claimed that the F.O.B. value of the subject merchandise entering the United States is greater than the F.O.B. price charged by the companies in Thailand (57 FR 26646; June 15, 1992). They explained that this discrepancy is due to a mark-up charged by the parent company, located in a third country, through which the merchandise is invoiced. However, the subject merchandise is shipped directly from Thailand to the United States and is not transshipped, combined with other merchandise, or repackaged with other merchandise. In other words, for each shipment of subject merchandise, there are two invoices and two corresponding F.O.B. export prices: (1) the F.O.B. export price at which the subject merchandise leaves Thailand, and on which subsidies from the Royal Thai Government (RTG) are earned by the companies, and upon which the subsidy rate is calculated; and (2) the F.O.B. export price which includes the parent company mark-up, and which is listed on the invoice accompanying the subject merchandise as it enters the United States, and upon which the cash deposits are collected and the countervailing duty is assessed. Respondents argued that the calculated *ad valorem* rate should be adjusted by the ratio of the export value from Thailand to the export value charged by the parent company to the U.S. customer so that the amount of countervailing duties collected would reflect the amount of subsidies bestowed. The Department agreed and made this adjustment in the first and second administrative reviews (57 FR 26646; June 15, 1992; and 58 FR 36392; July 7, 1993).

In the present review, we again verified, on a transaction-specific basis, the direct correlation between the invoice which reflects the F.O.B. price on which the subsidies are earned and the invoice which reflects the marked-up price that accompanies each shipment as it enters the United States. Since the mark-up is not part of the export value upon which the respondents earn bounties or grants, the Department has followed the methodology adopted in the first and second administrative reviews, and calculated the *ad valorem* subsidy rate as a percentage of the original export value from Thailand, multiplied by the adjustment ratio—the original export value from Thailand divided by the marked-up value of the same goods entering the United States.

We did not calculate a separate rate for each company because NMB Thai, Pelmec, and NMB Hi-Tech are wholly owned by one parent company, and are therefore related. As a result of this relationship, we considered the three companies as one corporate entity in our calculations. We calculated the bounty or grant by first totaling the benefits received by the three companies for each program used. Dividing these sums by total Thai export value for the three companies, we calculated the unadjusted bounty or grant for each program used. As described above, we adjusted these rates by multiplying them by the ratio of the original export price from Thailand to the marked-up price of the same goods entering the United States. Finally, we summed the adjusted bounty or grant for each program, to arrive at the total country-wide bounty or grant.

Analysis of Programs

Based upon our analysis of responses to our questionnaire and written comments from the interested parties, we determine the following:

I. Programs Conferring Subsidies

In the preliminary results, we found the following programs to be countervailable:

A. Investment Promotion Act (IPA) of 1977—Sections 31, 28, and 36(1)—4.27 percent *ad valorem*
B. Electricity Discounts for Exporters—0.02 percent *ad valorem*

Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change our findings in the preliminary results.

II. Programs Found Not To Be Used

In the preliminary results, we found that the Minebea Group did not apply for or receive benefits under the following programs during the period of review:

A. Tax Certificates for Exporters
B. Export Packing Credits
C. Rediscount of Industrial Bills
D. Export Processing Zones
E. IPA—Sections 33 and 36(4)
F. Reduced Business Taxes for Producers of Intermediate Goods for Export Industries
G. International Trade Promotion Fund

Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change our findings in the preliminary results.

Analysis of Comments

Comment: Respondents argue that the Department should adjust the calculations of the net subsidy and the deposit rate to account for the RTG's liftings of the export requirements for the Board of Investment Certificates of Promotion (BOI licenses) issued under the IPA program to the Minebea Group companies NMB Thai and NMB Hi-Tech and, with one exception, the BOI licenses issued to Minebea Group subsidiary Pelmec Thai. They argue that these liftings of requirements constitute a program-wide change as defined by section 355.50 of the *Notice of Proposed Rulemaking and Request for Public Comments,* 54 FR 23366, 23385 (May 31, 1989). *See* Respondents' Case Brief, page 2. They request that the Department deduct the amount of the benefits related to these liftings from the calculation of the net subsidy for the review period and consider for cash deposit purposes only the proportion of the production related to the one BOI license issued to Pelmec Thai for which the RTG did not lift the export requirements.

Petitioners argue that the Department should not adjust its calculations of the net subsidy and the deposit rate because (1) The removal of some export requirements in the BOI licenses did not eliminate all export requirements or constitute a program-wide change, and (2) the Thai government did not terminate the IPA program.

Department's Position: Under the IPA program, benefits are transmitted to IPA recipients through the recipients' BOI licenses. BOI licenses pertain to a promoted activity and list the IPA benefits for which the recipient is eligible, and the various conditions that must be met in order to receive those benefits. Although the BOI has lifted some of the export conditions for several of the Minebea Group's BOI licenses, IPA licensing benefits were nonetheless tied to export performance.

The Minebea Group has several BOI licenses pertaining to ball bearings. In January 1990, producers of electronic parts (BOI Category 4.6) became eligible to apply for the lifting of export requirements for their BOI licenses. Since ball bearings used in electronic products (electronic ball bearings) are classified under BOI Category 4.6, the Minebea Group applied for the lifting of export requirements for its BOI licenses pertaining to electronic ball bearings. The BOI awarded such liftings for several of the Minebea Group's BOI licenses, but the fact that the RTG only lifted the export requirements for certain IPA benefits applicable to certain types of ball bearings undermines respondents' argument that a program-wide change has taken place with respect to the IPA program as it applies to the subject merchandise.

Moreover, IPA licensing benefits received by the Minebea Group were tied to export performance. The IPA clearly states that the import duty exemption benefits under Section 36(1) (which is contained in licenses held by all three of the Minebea Group of companies) are conditional upon export of the final product, and these conditions were not lifted. With regard to benefits received under Section 31 (which exempts companies from payment of corporate income tax on profits derived from promoted activities), export requirements were in place during the tax year covered by the tax returns filed during the POR. That, in 1992 and 1993, the BOI retroactively lifted the export requirements of certain licenses does not change the fact that the Minebea Group of companies had to export the subject merchandise in order to claim benefits under Section 31. A similar argument holds for benefits received under Section 28.[1]

At the time its fixed assets were imported, most of the Minebea Group's licenses contained export requirements as a condition of receiving Section 28 benefits.

Not all of the BOI liftings were based upon BOI Category status. The export requirements for one of the Minebea Group's BOI licenses were lifted based on the fact that one of the Minebea Group's subsidiaries had a long-standing export history. Thus, the continued receipt of the benefits is contingent upon the fact that the company had an export history. Had the company been unable to demonstrate a history of export performance, the export requirements could not have been lifted under this decree.

Section 355.50 of the *Proposed Regulations* states that the term ''program-wide change'' means a change that is (1) not limited to an individual firm or firms and (2) effectuated by an official act, such as the enactment of a statute, regulation, or decree, or contained in the schedule of an existing statute, regulation, or decree. Since the changes in export requirements by the BOI were only for companies that had licenses for BOI Category 4.6 products and they had to be requested and approved on a license-by-license basis rather than applicable across the board, the BOI's actions do not constitute a program-wide change.

In conclusion, we will continue to countervail IPA licensing benefits received under Sections 36(1), 31, and 28. The RTG's liftings of certain export requirements for certain BOI licenses held by the Minebea Group do not constitute the outright elimination of export conditions with respect to the subject merchandise. Rather, IPA benefits continue to be contingent upon export performance with respect to ball bearings, the class or kind of merchandise subject to the countervailing duty order. As discussed above, export requirements were in place as a specific condition with respect to Section 36(1) benefits, and export performance criteria continued to exist with respect to the class or kind of merchandise for both Section 31 and Section 28 benefits. Furthermore, that producers of electronic parts were able to apply for and attain liftings of export requirements from certain BOI licenses does not constitute a program-wide change in the IPA program with respect to the subject merchandise covered in this review, ball bearings.

Final Results of Review

For the period January 1, 1992, through December 31, 1992, we determine the net subsidy to be 4.29 *ad valorem* for all companies. The Department will instruct the U.S. Customs Service to assess the following countervailing duties:

Manufacturer/exporter	Rate
All Companies	4.29

The Department will instruct the U.S. Customs Service to collect a cash deposit of estimated countervailing duties of 4.29 percent of the f.o.b. invoice price on all shipments of the subject merchandise from all companies.

This notice serves as a reminder to parties subject to administrative protective order (APO) of their

[1] Prior to the review period, IPA Section 28 allowed companies to import fixed assets free of import duties, the business tax and the local tax. However, effective January 1, 1992, the RTG eliminated both the business tax and the local tax and instituted a value added tax (VAT) system.

In the preliminary results of this administrative review, the Department determined that the exemption of the VAT on imports of fixed assets under Section 21(4) of the VAT Act does not constitute a countervailable benefit to the companies specified in Section 21(4). *See Ball Bearings and Parts Thereof from Thailand* (60 FR 22563). Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change this finding or our finding that the exemptions of import duties on fixed assets under Section 28 continue to provide countervailable benefits. However, as stated in the preliminary results, the Department will continue to examine provisions of the VAT Act, including Section 21(4), in future administrative reviews to ascertain that no countervailable benefits are being provided to manufacturers of subject merchandise.

responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 C.F.R. 355.34(d). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated September 29, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

Appendix A

Scope of the Review

The products covered by this review, ball bearings, mounted or unmounted, and parts thereof, are described below.

Ball Bearings, Mounted or Unmounted, and Parts Thereof

These products include all antifriction bearings which employ balls as the rolling element. During the review period, imports of these products were classifiable under the following categories: antifriction balls; ball bearings with integral shafts; ball bearings (including radial ball bearings) and parts thereof; ball bearing type pillow blocks and parts thereof; ball bearing type flange, take-up, cartridge, and hanger units, and parts thereof; and other bearings (except tapered roller bearings) and parts thereof. Wheel hub units which employ balls as the rolling element are subject to the review. Finished but unground or semiground balls are not included in the scope of this review. Imports of these products are currently classifiable under the following HTS item numbers: 8482.10.10, 8482.10.50, 8482.80.00, 8482.91.00, 8482.99.10, 8482.99.70, 8483.20.40, 8483.20.80, 8483.30.40, 8483.30.80, 8483.90.20, 8483.90.30, 8483.90.70, 8708.50.50, 8708.60.50, 8708.99.50.

This review covers all of the subject bearings and parts thereof outlined above with certain limitations. With regard to finished parts (inner race, outer race, cage, rollers, balls, seals, shields, etc.), all such parts are included in the scope of this review. For unfinished parts (inner race, outer race, rollers, balls, etc.), such parts are included if (1) they have been heat treated, or (2) heat treatment is not required to be performed on the part. Thus, the only unfinished parts that are not covered by this review are those where the part will be subject to heat treatment after importation.

[FR Doc. 95–24929 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DS–P

[C–549–802]

Ball Bearings and Parts Thereof From Thailand; Final Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Final Results of Countervailing Duty Administrative Review.

SUMMARY: On August 16, 1995, the Department of Commerce (the Department) published in the Federal Register its preliminary results of administrative review of the countervailing duty order on *Ball Bearings and Parts Thereof from Thailand* for the period January 1, 1993 through December 31, 1993. We have completed this review and determine the net subsidy to be 4.85 percent *ad valorem* for all companies. We will instruct the U.S. Customs Service to assess countervailing duties as indicated above.

EFFECTIVE DATE: October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Robert Copyak or Kelly Parkhill, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On August 16, 1995, the Department published in the Federal Register (60 FR 42532) the preliminary results of its administrative review of the countervailing duty order on *Ball Bearings and Parts Thereof from Thailand*. The Department has now completed this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

We invited interested parties to comment on the preliminary results. On September 15, 1995, a case brief was submitted by Pelmec Thai Ltd., NMB Thai Ltd., and NMB Hi-Tech Ltd. (three related companies, hereinafter the Minebea Group), producers/exporters of the subject merchandise during the review period (respondents). On September 15, 1995, a case brief was submitted by the Torrington Company (petitioner). On September 22, 1995, a rebuttal brief was submitted by respondents. The review covers the period January 1, 1993 through December 31, 1993. The review involves the Minebea Group of companies, which accounts for virtually all exports of subject merchandise from Thailand, and nine programs.

Applicable Statute and Regulations

The Department is conducting this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994. However, references to the Department's *Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments*, 54 FR 23366 (May 31, 1989) (*Proposed Regulations*), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the *Proposed Regulations* were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the Uruguay Round Agreements Act. *See* 60 FR 80 (Jan. 3, 1995).

Scope of the Review

Imports covered by this review are ball bearings and parts thereof. Such merchandise is described in detail in Appendix A to this notice. The *Harmonized Tariff Schedule* (HTS) item numbers listed in Appendix A are provided for convenience and Customs purposes. The written description remains dispositive.

Calculation Methodology for Assessment and Cash Deposit Purposes

In the first administrative review, respondents claimed that the F.O.B. value of the subject merchandise entering the United States is greater than the F.O.B. price charged by the companies in Thailand (57 FR 26646; June 15, 1992). They explained that this discrepancy is due to a mark-up charged by the parent company, located in a third country, through which the merchandise is invoiced. However, the subject merchandise is shipped directly from Thailand to the United States and is not transshipped, combined with other merchandise, or repackaged with other merchandise. In other words, for each shipment of subject merchandise, there are two invoices and two corresponding F.O.B. export prices: (1) the F.O.B. export price at which the subject merchandise leaves Thailand, and on which subsidies from the Royal Thai Government (RTG) are earned by the companies, and upon which the

subsidy rate is calculated; and (2) the F.O.B. export price which includes the parent company mark-up, and which is listed on the invoice accompanying the subject merchandise as it enters the United States, and upon which the cash deposits are collected and the countervailing duty is assessed. Respondents argued that the calculated *ad valorem* rate should be adjusted by the ratio of the export value from Thailand to the export value charged by the parent company to the U.S. customer so that the amount of countervailing duties collected would reflect the amount of subsidies bestowed. The Department agreed and made this adjustment in the first and second administrative reviews (57 FR 26646; June 15, 1992; and 58 FR 36392; July 7, 1993).

In prior reviews, we verified, on a transaction-specific basis, the direct correlation between the invoice which reflects the F.O.B. price on which the subsidies are earned and the invoice which reflects the marked-up price that accompanies each shipment as it enters the United States. Since the mark-up is not part of the export value upon which the respondents earn bounties or grants, the Department has followed the methodology adopted in the first and second administrative reviews, and calculated the *ad valorem* subsidy rate as a percentage of the original export value from Thailand, multiplied by the adjustment ratio—the original export value from Thailand divided by the marked-up value of the same goods entering the United States.

We did not calculate a separate rate for each company because NMB Thai, Pelmec, and NMB Hi-Tech are wholly owned by one parent company, and are therefore related. As a result of this relationship, we continue to consider, as we did in the investigation and previous reviews, the three companies as one corporate entity in our calculations. We calculated the bounty or grant by first totaling the benefits received by the three companies for each program used. Dividing these sums by total Thai export value for the three companies, we calculated the unadjusted bounty or grant for each program used. As described above, we adjusted these rates by multiplying them by the ratio of the original export price from Thailand to the marked-up price of the same goods entering the United States. Finally, we summed the adjusted bounty or grant for each program, to arrive at the total country-wide bounty or grant.

Analysis of Programs

Based upon our analysis of responses to our questionnaire and written comments from the interested parties, we determine the following:

I. Programs Conferring Subsidies

In the preliminary results, we found the following programs to be countervailable:

A. *Investment Promotion Act (IPA) of 1977—Sections 31, 28, and 36(1)*—4.85 percent *ad valorem*
B. *Electricity Discounts for Exporters*—less than .005 percent *ad valorem*

Our analysis of the comments submitted by the interested parties, summarized below, has led us to change the result in our preliminary results from 1.33 to 4.85 percent *ad valorem*.

II. Programs Found Not To Be Used

In the preliminary results, we found that the Minebea Group did not apply for or receive benefits under the following programs during the period of review:

A. *Tax Certificates for Exporters*
B. *Export Packing Credits*
C. *Rediscount of Industrial Bills*
D. *Export Processing Zones*
E. *IPA—Sections 33 and 36(4)*
F. *Reduced Business Taxes for Producers of Intermediate Goods for Export Industries*
G. *International Trade Promotion Fund*

Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change our findings in the preliminary results.

Analysis of Comments

Comment 1: Respondents argue that the Department should adjust the calculations of the net subsidy and the deposit rate to account for the RTG's liftings of export requirements for the Board of Investment Certificates of Promotion (BOI licenses) issued under the IPA program to the Minebea Group of companies NMB Thai and NMB Hi-Tech, and, with one exception, the BOI licenses issued to Minebea Group company Pelmec Thai. They request that the Department deduct the amount of the benefits related to these liftings from the calculation of the net subsidy for the review period and consider for cash deposit purposes only the proportion of the production related to the one BOI license issued to Pelmec Thai for which the RTG did not lift the export requirements.

Petitioners argue that, since the amendments made in the BOI licenses did not eliminate all export requirements or constitute a program-wide change, the licensing benefits of the IPA program remain countervailable. They also point out that the IPA program remains countervailable because of regional eligibility requirements and export requirements related to foreign-owned companies such as the Minebea Group.

Department's Position: Under the IPA program, benefits are transmitted to IPA recipients through the recipients' BOI licenses. BOI licenses pertain to a promoted activity and list the IPA benefits for which the recipient is eligible, and the various conditions that must be met in order to receive those benefits. Although the BOI has lifted some of the export conditions for several of the Minebea Group's BOI licenses, IPA licensing benefits were nonetheless tied to export performance.

Because these liftings do not constitute a program-wide change, the IPA program remains countervailable. The Minebea Group has several BOI licenses pertaining to ball bearings. In January 1990, producers of electronic parts (BOI category 4.6) became eligible to apply for the lifting of export requirements for their BOI licenses. Since ball bearings used in electronic products (electronic ball bearings) are classified under BOI Category 4.6, the Minebea Group applied for the lifting of export requirements for its BOI licenses pertaining to electronic ball bearings. The BOI awarded such liftings for several of the Minebea Group's BOI licenses. However, the lifting of the export requirements for certain IPA benefits applicable to certain types of ball bearings does not constitute a program-wide change with respect to the class or kind of merchandise. Section 355.50 of the *Proposed Regulations* states that the term ''program-wide change'' means a change that is (1) not limited to an individual firm or firms and (2) effectuated by an official act, such as the enactment of a statute, regulation, or decree, or contained in the schedule of an existing statute, regulation, or decree. Since the changes in export requirements by the BOI were only for companies that had licenses for BOI Category 4.6 products and they had to be requested and approved on a license-by-license basis rather than applicable across the board, the BOI's actions do not constitute a program-wide change.

Moreover, the IPA licensing benefits received by the Minebea Group were tied to export performance. The IPA clearly states that the import duty exemption benefits under Section 36(1) (which is contained in licenses held by all three of the Minebea Group of companies) are conditional upon export of the final product, and these conditions were not lifted. With regard to benefits received under Section 31

(which exempts companies from payment of corporate income tax on profits derived from promoted activities), export requirements were in place during the tax year covered by the tax returns filed during the POR. That the BOI retroactively lifted the export requirements of certain licenses does not change the fact that the Minebea Group of companies had to export the subject merchandises in order to claim benefits under Section 31. A similar argument holds for benefits received under Section 28.[1] During the review period, the Minebea Group were able to import fixed assets with licenses which contained export requirements as a condition of receiving Section 28 benefits.

Not all of the BOI liftings were based upon BOI Category status. The export requirements for one of the Minebea Group's BOI licenses were lifted based on the fact that one of the Minebea Group's subsidiaries had a long-standing export history. Thus, the continued receipt of the benefits is contingent upon the fact that the company had an export history. Had the company been unable to demonstrate a history of export performance, there is no evidence that export requirements could have been lifted under this decree. *See* Exhibit 23 of the public version of respondents' December 12, 1994 questionnaire response.

As explained in our preliminary results, effective April 1, 1993, all types of ball bearings and parts thereof were reclassified under industrial category 4.8, ''Manufacture of fabricated metal products, including metal parts for automotive and electronic products.'' In addition, new policies and criteria issued by the BOI stipulate that tax and duty privileges for promoted projects approved after April 1, 1993 are contingent upon location of the promoted company in one of three types of investment promotion zones. Therefore, promoted projects approved after April 1, 1993 for products classified under category 4.8 must be located in industrial promotion zones 2 or 3. In addition, export performance is a criterion for approval of promoted projects involving companies which are wholly or significantly foreign-owned.

In conclusion, IPA licences conferred countervailable benefits during the review period, and there has not been a program-wide change which would warrant an adjustment of the cash deposit rate. The RTG's liftings of certain export requirements for certain BOI licenses held by the Minebea Group do not constitute the outright elimination of export conditions with respect to the subject merchandise. Rather, IPA benefits continue to be contingent upon export performance with respect to ball bearings, the class or kind of merchandise subject to the countervailing duty order. As discussed above, export requirements were in place as a specific condition with respect to Section 36(1) benefits, and export performance criteria continued to exist with respect to the class or kind of merchandise for both Section 31 and Section 28 benefits.

Comment 2: Petitioner alleges that, in the preliminary results, there was a clerical error in the calculation of the mark-up adjustment.

Department's Position: We agree. We used an incorrect figure in the calculation. Using the correct mark-up ratio, we calculate the net subsidy rate to be 4.85 percent *ad valorem*.

Final Results of Review

For the period January 1, 1992, through December 31, 1992, we determine the net subsidy to be 4.85 percent *ad valorem* for all companies.

The Department will instruct the U.S. Customs Service to assess the following countervailing duties:

Manufacturer/exporter	Rate
All Companies	4.85

The Department will instruct the U.S. Customs Service to collect a cash deposit of estimated countervailing duties of 4.85 percent *ad valorem* of the f.o.b. invoice price on all shipments of the subject merchandise from all companies.

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 C.F.R. 355.34(d). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: September 29, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

Appendix A

Scope of The Review

The products covered by this review, ball bearings, mounted or unmounted, and parts thereof, are described below.

Ball Bearings, Mounted or Unmounted, and Parts Thereof

These products include all antifriction bearings which employ balls as the rolling element. During the review period, imports of these products were classifiable under the following categories: antifriction balls; ball bearings with integral shafts; ball bearings (including radial ball bearings) and parts thereof; ball bearing type pillow blocks and parts thereof; ball bearing type flange, take-up, cartridge, and hanger units, and parts thereof; and other bearings (except tapered roller bearings) and parts thereof. Wheel hub units which employ balls as the rolling element are subject to the review. Finished but unground or semiground balls are not included in the scope of this review. Imports of these products are currently classifiable under the following HTS item numbers: 8482.10.10, 8482.10.50, 8482.80.00, 8482.91.00, 8482.99.10, 8482.99.70, 8483.20.40, 8483.20.80, 8483.30.40, 8483.30.80, 8483.90.20, 8483.90.30, 8483.90.70, 8708.50.50, 8708.60.50, 8708.99.50.

This review covers all of the subject bearings and parts thereof outlined above with certain limitations. With regard to finished parts (inner race, outer race, cage, rollers, balls, seals, shields, etc.), all such parts are included in the scope of this review. For unfinished parts (inner race, outer race, rollers, balls, etc.), such parts are included if (1) they have been heat treated, or (2) heat treatment is not required to be performed on the part. Thus, the only unfinished parts that are not covered by this review are those where the part will be subject to heat treatment after importation.

[FR Doc. 95–24930 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DS–P

[1] Prior to the review period, IPA Section 28 allowed companies to import fixed assets free of import duties, the business tax and the local tax. However, effective January 1, 1992, the RTG eliminated both the business tax and the local tax and instituted a value added tax (VAT) system. In the preliminary results of this administrative review, the Department determined that the exemption of the VAT on imports of fixed assets under Section 21(4) of the VAT Act does not constitute a countervailable benefit to the companies specified in Section 21(4). *See Ball Bearings and Parts Thereof from Thailand* (60 FR 42532). Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change this finding or our finding that the exemptions of import duties on fixed assets under Section 28 continue to provide countervailable benefits. However, as stated in the preliminary results, the Department will continue to examine provisions of the VAT Act, including Section 21(4), in future administrative reviews to ascertain that no countervailable benefits are being provided to manufacturers of subject merchandise.

[C–559–802]

Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof (AFBs) From Singapore; Final Results of Countervailing Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of countervailing duty administrative reviews.

SUMMARY: On August 4, 1995 (60 FR 39933), the Department of Commerce (the Department) published in the Federal Register its preliminary results of administrative reviews of the countervailing duty orders on antifriction bearings (other than tapered roller bearings) and parts thereof (AFBs) from Singapore for the periods January 1, 1992 through December 31, 1992, and January 1, 1993 through December 31, 1993. We have completed these reviews and determine the net subsidy to be zero during both periods for the Minebea group of companies (Pelmec Industries (Pte.) Ltd., NMB Singapore Ltd, and Minebea Co. Ltd. Singapore Branch), and 9.11 percent *ad valorem* for all other companies. The Department will instruct the Customs Service to liquidate, without regard to countervailing duties, all shipments of the subject merchandise from Singapore exported by the Minebea group of companies on or after January 1, 1992 and on or before December 31, 1993. For all other companies, will instruct the U.S. Customs Service to assess countervailing duties as indicated above.

EFFECTIVE DATE: October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Brian Albright or Cameron Cardozo, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On August 4, 1995, the Department published in the Federal Register (60 FR 39933) the preliminary results of its administrative reviews of the countervailing duty orders on AFBs from Singapore. The Department has now completed these administrative reviews in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

We invited interested parties to comment on the preliminary results. On September 5, 1995, a case brief was submitted jointly by respondents, the Government of Singapore (GOS) and the Minebea group, producers of the subject merchandise which exported to the United States during the review period. On September 12, 1995, the petitioner, the Torrington Company, submitted rebuttal comments.

The reviews cover the periods January 1, 1992 through December 31, 1992 and January 1, 1993 through December 31, 1993. The 1992 reviews involve three related companies and 16 programs. The 1993 reviews cover the same companies and 17 programs.

Applicable Statute and Regulations

The Department is conducting this administrative review in accordance with section 751(a) of the Act. Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994. However, references to the Department's Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments, 54 FR 23366 (May 31, 1989) (*Proposed Regulations*), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the Proposed Regulations were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the Uruguay Round Agreements Act. See 60 FR 80 (Jan. 3, 1995).

Scope of the Reviews

Imports covered by these reviews are shipments of antifriction bearings (other than tapered roller bearings) and parts thereof. The subject merchandise covers five separate classes or kinds of merchandise, each of which is described in detail in Appendix A to this notice. The Harmonized Tariff Schedule item numbers listed in Appendix A are provided for convenience and Customs purposes. The written descriptions remain dispositive.

On October 30, 1992, the Department received a request for a scope determination from Sundstrand Pacific (Sundstrand). Specifically, Sundstrand asked the Department to find its part number 742973, an outer-race of the cylindrical roller bearing, not within the scopes of the countervailing duty orders. The request was subsequently evaluated in accordance with section 355.29(i)(1) of the Department's regulations. On February 4, 1993, the Department determined that the product in question was within the scope of the order on cylindrical roller bearings (58 FR 27542, 27543; May 10, 1993). Because the product descriptions detailed in Sundstrand's request for a scope determination were dispositive as to whether part number 742973 was within the scope of the order on cylindrical roller bearings, the Department did not initiate a formal scope inquiry. Accordingly, the U.S. Customs Service has been instructed to continue to suspend liquidation of part 742973 exported by Sundstrand.

Best Information Available

During the investigation, Sundstrand, an exporter of the subject merchandise which was identified by the Government of Singapore (GOS), refused to participate, and consequently received a rate based entirely on best information available (BIA)(see Final Affirmative Countervailing Duty Determinations and Countervailing Duty Orders: Antifriction Bearings (other than Tapered Roller Bearings) and Parts thereof from Singapore (54 FR 19125, 19126; May 3, 1989)). Section 776(c) of the Act requires the Department to use BIA ''whenever a party or any other person refuses or is unable to produce information requested in a timely manner and in the form required, or otherwise significantly impedes an investigation * * *'' *See also* 19 CFR § 355.37.

In determining what rate to use as BIA, the Department follows a two-tiered methodology. The Department normally assigns lower BIA rates to those respondents who cooperate in an administrative review (tier two) and rates based on more adverse assumptions for respondents who do not cooperate in the review, or who significantly impede the proceeding (tier one). *Cf. Allied Signal Aerospace Co.* v. *United States*, 996 F. 2d 1185 (Fed. Cir. 1993), *aff'd*, 28 F. 3d 1188, *cert. denied*, 1995 U.S. Lexis 100 (1995) (*Allied-Signal*).

In these reviews, only the three related Minebea companies, which account for the majority of Singaporean exports to the United States of the subject merchandise, responded to the Department's questionnaires. Sundstrand did not respond to our questionnaires. Furthermore, during the course of verification of the GOS questionnaire response for 1992, we examined a list of companies which exported subject merchandise to the United States but, for reasons unknown

to the Department, did not respond to our questionnaire (See April 8, 1994, memorandum to Barbara E. Tillman (Public Version) regarding Verification of Questionnaire Response in 1992 Administrative Review of CVD Order on Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From Singapore—Covering the Period January 1, 1992 through December 31, 1992, at 4, which is on file in the public file of the Central Records Unit, Room B–099 of the Department of Commerce). The GOS did not provide any information regarding Sundstrand or the other companies' sales or exports of the subject merchandise, or the extent to which Sundstrand or these companies participated in the programs reviewed. During the course of the 1993 verification of the GOS questionnaire response, we again examined a list of companies which exported subject merchandise to the United States but did not respond to our questionnaire (See April 9, 1995, memorandum to Barbara E. Tillman (Public Version) regarding Verification of Questionnaire Responses in the 1993 Administrative Review of Countervailing Duty Order on Antifriction Bearings (Other Than Tapered Roller Bearings) From Singapore, at 3, which is on file in the public file of the Central Records Unit, Room B–099 of the Department of Commerce). Again, the GOS did not provide any information regarding Sundstrand or the other companies' sales or exports of the subject merchandise, or the extent to which they participated in the programs reviewed. Therefore, in accordance with section 776(c) of the Act and Allied-Signal, we are assigning to Sundstrand and all other non-respondent companies a first-tier uncooperative BIA rate for both periods of review. The rate we are applying for the periods January 1, 1992, through December 31, 1992, and January 1, 1993, through December 31, 1993, is 9.11 percent *ad valorem*. This rate is the rate that has been assigned to Sundstrand in each review since the first administrative review (see Final Results of Countervailing Duty Administrative Review: Antifriction Bearings (other than Tapered Roller Bearings) and Parts thereof from Singapore (56 FR 26384; June 7, 1991)).

Calculation Methodology for Assessment and Cash Deposit Purposes

In accordance with our standard practice, for both periods of review, we calculated the net subsidy on a country-wide basis by first calculating the subsidy rate for each company subject to the administrative review. We then weight-averaged the rate received by each company using as the weight the company's share of total exports from Singapore to the United States of subject merchandise, including all companies, even those with *de minimis* and zero rates. To determine the value of exports for the Minebea group of companies, we added the reported total exports of subject merchandise to the United States by the two related producers/exporters, NMB Singapore Ltd. and Pelmec (Pte.) Ltd., to the total net mark-up on exports of subject merchandise to the United States reported by the related trading company respondent, Minebea Singapore Ltd. To determine the value of exports for Sundstrand and all other non-respondent companies based on BIA (see Best Information Available, above), we subtracted the value of the Minebea companies' exports of subject merchandise to the United States from the total value of exports of subject merchandise to the United States, as reported by the GOS.

We then summed the individual weight-averaged rates to determine the subsidy from all programs benefitting Singaporean exports of subject merchandise to the United States. Because the country-wide rate calculated using this methodology was above *de minimis,* as defined by 19 CFR § 355.7, for both periods of review, we next examined the net subsidy rate calculated for each company to determine whether individual company rates differed significantly from the weighted-average country-wide rate, pursuant to 19 CFR § 355.22(d)(3).

For both periods of review, we found that the Minebea group of companies and the non-respondent companies had significantly different net subsidy rates (zero and 9.11 percent *ad valorem,* respectively). Under the Department's practice, any companies which did not have a significantly different rate would be assigned the country-wide rate. See *Ceramica Regiomontana* v. *United States* 853 F. Supp. 431,439 (CIT 1994). However, because we are applying BIA to all other companies besides the Minebea group (See Best Information Available, above), we are not issuing a weighted-average country-wide rate.

Analysis of Programs

Based upon our analysis of the questionnaire responses, verification, and written comments from petitioner and respondents we determine the following:

I. Program Found Not to Confer Subsidies

In the preliminary results we found the following program to be non-countervailable:

Investment Allowances Under Part X of the Economic Expansion Incentives Act (EEIA)

Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change our findings in the preliminary results.

II. Programs Found Not To Be Used

In the preliminary results we found the following programs to be not used during both the 1992 and 1993 review periods:

A. Production for Export under Part VI of the EEIA
B. Monetary Authority of Singapore Rediscount Facility
C. Other Tax Incentives under the EEIA
- Part IV: Expansion of Established Enterprises
- Part VII: International Trade Incentives
- Part VIII: Foreign Loans for Productive Equipment
- Part IX: Royalties, Fees and Development Contributions
- Part XI: Warehousing and Servicing Incentives

D. Incentives Under the Income Tax Act
- Sections 14B and 14C: Double Deduction of Export Promotion Expenses
- Section 14E: Double Deduction for Research and Development
- Section 19B: Write-Offs of Payments for ''Know-How'', Patents and Manufacturing Licenses

E. Programs Administered by the Economic Development Board
- Capital Assistance Scheme
- Productive Development Assistance Scheme
- Initiatives in New Technology Program

F. Program Administered by the National Science Technology Board: Research & Development Assistance Scheme

In addition, for the 1993 review, we found that the producers/exporters of the subject merchandise did not apply for or receive benefits under Part IIIA of the EEIA (post-pioneer status).

Analysis of Comments

Comment: The petitioner argues that the record evidence does not support the Department's preliminary conclusion that Part X of the EEIA is not limited to a specific enterprise or industry or a group of enterprises or industries. Petitioner states that AFBs, accounting for only a fraction of the production and sales of one of 69 industry categories, represented less than one percent of all industries; as such, it accounted for a disproportionate

share of the allowances received by all industries. Petitioner also points out the Department's analysis showing that AFBs producers, who received two (or 0.6 percent) of the 329 grants made under the program over a four-year period, accounted for 6.3 percent of the total value of those grants. (*See* December 30, 1994 Memorandum to Barbara E. Tillman Regarding *1992 and 1993 Administrative Reviews of Antifriction Bearings (AFBs) from Singapore—Investment Allowance Program, Part X of the Economic Expansion Incentives Act (EEIA),* on file in the public file of the Central Records Unit, Room B–099 of the Department of Commerce) (*Analysis Memo*). Moreover, petitioner argues, the fact that one industry sector (electronics) received more benefits under Part X than the sector which includes AFBs (fabricated metal products) does not preclude the Department from finding that the AFBs is a dominant user. Congress' intention with respect to the specificity test, petitioner states, is to differentiate between government assistance that is broadly available and widely used and subsidies provided to discrete segments of the economy, and not to function as a loophole through which narrowly focused subsidies provided to discrete segments of an economy could escape the purview of the CVD law. (*See* Statement of Administrative Action, H. Doc. 103–316, 103d Cong., 2d Sess. 929–30 (1994)). Petitioner again refers to the Department's *Analysis Memo* showing that three industry sectors (electronics, fabricated metal products, and non-electrical machinery) accounted for 71 percent of the total allowances provided. As such, petitioner argues that benefits bestowed to AFBs producers under Part X are countervailable subsidies.

Department's Position: We disagree with petitioner. The Department conducts its specificity test on a case-by-case basis, taking into account all information on the record. The test requires, among other things, that the Department consider several factors. See 19 U.S.C. 1677(5)(B), and Proposed Regulations, at section 355.43(b)(2). The factors of our analysis, listed in the order of consideration, are the following: (i) the extent to which a government acts to limit the availability of a program (the Department has consistently interpreted this factor as providing for the *de jure* analysis. See, e.g. Fresh, Chilled, and Frozen Pork from Canada, 54 FR 30744, 30777 (1989)); (ii) the number of enterprises, industries, or groups thereof that actually use a program; (iii) whether there are dominant users of a program, or whether certain enterprises, industries, or groups thereof receive disproportionately large benefits under a program; and (iv) the extent to which a government exercises discretion in conferring benefits under a program. *Proposed Regulations,* at § 355.43(b)(2).

Petitioner's comments address the third factor of specificity analysis, whether there are dominant or disproportionate users of the program. Petitioner suggests two comparisons as being indicative of disproportionality, one between the number of industry categories receiving allowances and the value of the allowances received, and the other between the number of allowances and the value of the allowances. Petitioner's use of these comparisons is neither indicative nor informative of whether disproportionate benefits have been bestowed. The fact that AFBs received only 0.6 percent of the number of allowances under Part X (or represented less than one percent of the number of industries) but 6.3 percent of the total value of allowances bestowed is not evidence of disproportionality under the Department's practice.

In prior cases where the Department has found disproportionality (See Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Brazil (Certain Steel), 58 FR 37295 (July 9, 1993); Final Affirmative Countervailing Duty Determination: Grain-Oriented Electrical Steel From Italy (Electrical Steel), 59 FR 18357, 18360 (April 18, 1994); Live Swine from Canada; Final Results of Countervailing Duty Administrative Review (Live Swine), 59 FR 12243 (March 16, 1994), we analyzed whether respondents received a disproportionate share of benefits by comparing their share of benefits to the collective or individual share of benefits provided to all other users of the program in question. Similarly, in this case, we compared the share of benefits received by AFBs under Part X to the individual and collective share of benefits provided to all others. The share of Part X benefits received by AFBs was only 6.3 percent of the total value of allowances received by all users. In Certain Steel, by contrast, steel producers accounted for more than 50 percent of the benefits under the examined program. The small amount of benefits received by AFBs producers is also distinguishable from Electrical Steel, in which steel producers received 34 percent of the benefits, and Live Swine, in which hog producers received 70 percent of the total benefits under the examined program.

Moreover, we do not find persuasive petitioner's argument that, as part of one of three industry categories which collectively received 71 percent of the allowances approved, AFBs received a disproportionate share. While it is possible for a group of industries to be a ''disproportionately large'' recipient of benefits based on the facts of a given case (See Certain Steel and Electrical Steel), in this instance we are dealing with three industry categories which include a wide variety of distinct and diverse products, not variations of the same product or the same product at different stages of production. As petitioner has acknowledged in its comments, AFBs are only part of the fabricated metal products category. This category also includes toolings, fasteners, springs, wireforms, stamping equipment, and many other products, all of which received allowances. Furthermore, the products with approved allowances in the electronics category include circuit boards, television components, microwave units, semiconductors, telephones, audio webs, and other products. See Verification Report (Public Version) for the 1992 Administrative Review, May 8, 1995, at 19, which is on file in the public file of the Central Records Unit, Room B–099 of the Department of Commerce. Thus, while the fact that three industry categories collectively accounted for 71 percent of the value of total allowances may, on its face, appear significant, when all of the information regarding the usage of the program is analyzed, this number alone is not sufficient to find that AFBs received a disproportionate share.

We agree with petitioner's assertion that the specificity test is not intended to function as a loophole through which narrowly focused subsidies provided to discrete segments of an economy escape the purview of the CVD law. However, in our analysis, we found no evidence that Part X is a narrowly focused subsidy provided to AFBs. Rather, the Department has found the broad distribution of Part X benefits among companies and industries in Singapore to be indicative that the program is widely available and used by more than just ''discrete segments'' of the economy. Therefore, our preliminary finding regarding Part X remains unchanged.

Final Results of Review

For the periods January 1, 1992 through December 31, 1992 and January 1, 1993 through December 31, 1993, we determine the net subsidy to be zero for the Minebea group of companies and

9.11 percent *ad valorem* for all other companies.

The Department will instruct the U.S. Customs Service to assess the following countervailing duties:

Manufacturer/exporter	Rate (percent)
Minebea Companies (Pelmec, NMB, and MSB)	0.00
All Other Companies percent	9.11

The Department will also instruct the U.S. Customs Service to collect zero cash deposits of estimated countervailing duties on all shipments of the subject merchandise from Singapore by the Minebea group of companies, and 9.11 percent of the f.o.b. invoice price on all shipments of the subject merchandise from all other companies, entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 C.F.R. 355.34(d). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: September 29, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–24931 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DS–P

[C–357–404]

Certain Apparel From Argentina; Final Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of countervailing duty administrative review.

SUMMARY: On August 16, 1995, the Department of Commerce (the Department) published in the Federal Register its preliminary results of administrative review of the countervailing duty order on certain apparel from Argentina for the period January 1, 1991 through December 31, 1991. We have completed this review and determine the net subsidy to be zero for Agrest, S.A. (Agrest), Comercio Internacional, S.A. (Comercio), IVA, S.A. (IVA), and Leger, S.A. (Leger), 15.87 percent *ad valorem* for Pulloverfin, S.A. (Pulloverfin) and 0.76 percent *ad valorem* for all other companies. We will instruct the U.S. Customs Service to assess countervailing duties as indicated above.

EFFECTIVE DATE: October 6, 1995.

FOR FURTHER INFORMATION CONTACT: Judy Kornfeld or Lorenza Olivas, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On August 16, 1995, the Department published in the Federal Register (60 FR 42530) the preliminary results of its administrative review of the countervailing duty order on certain apparel from Argentina. The Department has now completed this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act). We invited interested parties to comment on the preliminary results. We received no comments. The review covers the period January 1, 1991 through December 31, 1991. The review involves 5 companies and 10 programs.

Applicable Statute and Regulations

The Department is conducting this administrative review in accordance with section 751(a) of the Act. Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994. However, references to the Department's *Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments,* 54 FR 23366 (May 31, 1989) (*Proposed Regulations*), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the Proposed Regulations were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the Uruguay Round Agreements Act. *See* 60 FR 80 (Jan. 3, 1995).

Scope of the Review

The subject merchandise is certain apparel from Argentina. During the review period, this merchandise was classifiable under the following HTS numbers, which are based on the amended conversion of the scopes of the countervailing duty order. *See Certain Textile Mill Products From Mexico, Certain Apparel From Argentina, and Certain Apparel From Thailand* (58 FR 4151; January 13, 1993).

6104.41.00, 6104.43.10, 6104.44.10, 6104.51.00, 6104.53.10, 6104.61.00, 6104.63.15, 6105.10.00, 6105.20.20, 6106.10.00, 6106.20.10, 6106.90.10, 6109.90.20, 6110.10.20, 6110.20.20, 6111.10.00, 6112.41.00, 6112.49.00, 6115.20.00, 6115.91.00, 6115.93.10, 6115.99.14, 6116.91.00, 6116.93.15, 6201.12.20, 6202.11.00, 6202.13.30, 6202.91.10, 6202.91.20, 6202.92.20, 6202.93.40, 6203.22.30, 6203.42.40, 6204.11.00, 6204.13.10, 6204.19.10, 6204.21.00, 6204.31.20, 6204.33.40, 6204.39.20, 6204.41.20, 6204.42.30, 6204.43.30, 6204.44.30, 6204.51.00, 6204.53.20, 6204.59.20, 6204.61.00, 6204.63.25, 6204.69.20, 6205.10.20, 6206.20.30, 6206.40.25, 6209.10.00, 6209.20.10, 6209.20.50, 6209.90.30, 6211.12.30, 6211.41.00, 6214.30.00, 6214.40.00.

Best Information Available (BIA) for Pulloverfin

Section 776(c) of the Act requires the Department to use BIA ''whenever a party or any other person refuses or is unable to produce information requested in a timely manner and in the form required, or otherwise significantly impedes an investigation.''

In determining what rate to use as BIA, the Department follows a two-tiered methodology. The Department normally assigns lower BIA rates for those respondents who cooperated in an

administrative review (tier two) and rates based on more adverse assumptions for respondents who do not cooperate in the review, or who significantly impede the proceeding (tier one). *Cf. Allied Signal Aerospace Co.* v. *United States*, 996 F. 2d 1185 (Fed. Cir. 1993), *aff'd*, 28 F. 3d 1188, *cert. denied*, 1995 U.S. lexis 100 (1995) (*Allied-Signal*). *See also Final Results of Countervailing Duty Administrative Review: AFBs from Singapore* (58 FR 47122; September 7, 1993).

In this review, Pulloverfin did not respond to the Department's two requests for information; therefore, we are assigning Pulloverfin a tier one rate based on BIA. The rate we are applying is 15.87 percent *ad valorem*. This rate reflects the rate Pulloverfin received in the investigation (*see Final Affirmative Countervailing Duty Determinations and Countervailing Orders: Certain Textile Mill Products and Apparel from Argentina* (50 FR 9846; March 12, 1985)).

Calculation Methodology for Assessment and Cash Deposit Purposes

We calculated the net subsidy on a country-wide basis by first calculating the subsidy rate for each company subject to the administrative review. We then weight-averaged the rate received by each company using as the weight its share of total Argentine exports to the United States of subject merchandise, including all companies, even those with *de minimis* and zero rates. We then summed the individual companies' weight-averaged rates to determine the subsidy rate from all programs benefitting exports of subject merchandise to the United States.

Since the country-wide rate calculated using this methodology was above *de minimis*, as defined by 19 CFR § 355.7 (1994), we proceeded to the next step, and examined the net subsidy rate calculated for each company to determine whether individual company rates differed significantly from the weighted-average country-wide rate, pursuant to 19 CFR § 355.22(d)(3). All companies subject to the review had significantly different net subsidy rates during the review period pursuant to 19 CFR § 355.22(d)(3). These companies are treated separately for assessment and cash deposit purposes. All other companies are assigned the country-wide rate. *See Ceramica Regiomontana S.A.* v. *United States*, 853 F Supp. 431, 439 (CIT 1994).

Analysis of Programs

Based upon our analysis of the questionnaire response we determine the following:

I. Programs Conferring Bounties or Grants

Rebate of Indirect Taxes (Reembolso/Reintegro)

In the preliminary results we found this program to be countervailable. However, the program conferred no benefits on the subject merchandise during the period of review (POR). Since we received no comments on our preliminary results, our findings remain unchanged in these final results.

II. Programs Found Not to be Used

In the preliminary results we found that the producers and/or exporters of the subject merchandise did not apply for or receive benefits under the following programs during the period of review:

A. Tax Deduction Under Decree 173/85
B. Exemption from Stamp Taxes Under Decree 186/74
C. Industrial Parks
D. Low Cost Loans for Projects Outside Buenos Aires
E. Tucaman Regional Tax Incentives
F. Patagonion Regional Tax Incentives
G. Incentives for Exports from Southern Ports
H. Corrientes Regional Tax Incentive
I. Export Financing

Since we received no comments on our preliminary results, our findings remain unchanged in these final results.

Final Results of Review

For the period January 1, 1991 through December 31, 1991, we determine the net subsidy to be zero for Agrest, Comercio, IVA and Leger, 15.87 percent *ad valorem* for Pulloverfin and 0.76 percent *ad valorem* for all other companies.

The Department will instruct the U.S. Customs Service to assess the following countervailing duties:

Manufacturer/exporter	Rate
Agrest, Comercio, IVA and Leger	0.00
Pulloverfin	15.87
All other companies	0.76

The Department will instruct the U.S. Customs Service to collect a cash deposit of estimated countervailing duties of zero percent of the F.O.B. invoice price on all shipments of the subject merchandise from Agrest, Comercio, IVA and Leger, and to collect a cash deposit of 15.87 percent *ad valorem* of the F.O.B. invoice price on all shipments of the subject merchandise from Pulloverfin and 0.76 percent *ad valorem* of the F.O.B. invoice price on shipments of the subject merchandise from all other companies entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review.

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 C.F.R. 355.34(d). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: September 29, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–24932 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DS–P

National Institute of Standards and Technology

[Docket Number 950130031–5212–02]

Voluntary Product Standard; PS 1–95 ''Construction and Industrial Plywood''

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) announces Voluntary Product Standard PS 1–95, a revision of Voluntary Product Standard PS 1–83 ''Construction and Industrial Plywood.'' The Standard provides basic technical requirements for the principal types and grades of construction and industrial plywood. It covers wood species, veneer grading, glue bonds, panel construction and workmanship, dimensions and tolerances, marking, moisture content, and packing of plywood intended for construction and industrial uses. Included in the Standard are test methods to determine product compliance, a glossary of trade terms and definitions, and a quality certification program. In addition, information regarding reinspecting practices is provided.

ADDRESSES: Copies of PS 1–95 may be obtained from Barbara Meigs, Office of Standard Services, National Institute of Standards and Technology, Room 121, Building 417, Gaithersburg, MD 20899.

FOR FURTHER INFORMATION CONTACT: Barbara Meigs, telephone: 301–975–4025, FAX: 301–963–2871.

SUPPLEMENTARY INFORMATION: PS 1–95, a revision of PS 1–83, was developed by the Standing Committee for Voluntary Product Standard PS 1. The Committee is composed of representatives of producers, distributors, and consumers of construction and industrial plywood, and others with an interest in the Standard. NIST published a notice in the Federal Register on February 21, 1995 (60 FR 9670) that it was circulating the standard for public review and comment. The revision was processed in accordance with the provisions of the Department of Commerce ''Procedures for the Development of Voluntary Product Standards'' (15 CFR Part 10, as amended; 51 FR 119 dated June 20, 1986). A 75-day public comment period was allowed.

Public responses to the revision indicated consensus among producers, distributors, users, and consumers in accordance with Department procedures. The Standard was approved to supersede PS 1–83, effective September 7, 1995. New to PS 1–95 is the incorporation of a performance-based method for evaluating new species, judged desirable because of the changing available timber resource for plywood production; and the elimination of Structural II panel grades based on the fact that this product had rarely been manufactured since it was first introduced in PS 1–66. In some instances, the text has been reformatted, and throughout the Standard, units of measurement are provided in both metric and conventional units.

Authority: 15 USC 272.

Dated: October 2, 1995.

Samuel Kramer,

Associate Director.

[FR Doc. 95–24917 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–13–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Taiwan

October 2, 1995.

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

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

EFFECTIVE DATE: October 4, 1995.

FOR FURTHER INFORMATION CONTACT: Jennifer Aldrich, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–6719. For information on embargoes and quota re-openings, call (202) 482–3715.

T2SUPPLEMENTARY INFORMATION:

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

The current limits for certain categories are being adjusted, variously, for swing, special shift, carryover and carryforward used.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 59 FR 65531, published on December 20, 1994). Also see 59 FR 66297, published on December 23, 1994.

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.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

October 2, 1995.

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

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 19, 1994, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Taiwan and exported during the twelve-month period which began on January 1, 1995 and extends through December 31, 1995.

Effective on October 4, 1995, you are directed to amend further the December 19, 1994 directive to adjust the limits for the following categories, as provided under the terms of the current bilateral textile agreement concerning textile products from Taiwan:

Category	Twelve-month limit [1]
Group I	
200–224, 225/317/326, 226, 227, 229, 300/301/607, 313–315, 360–363, 369–L/670–L/870 [2], 369–S [3], 369–O [4], 400–414, 464–469, 600–606, 611, 613/614/615/617, 618, 619/620, 621–624, 625/626/627/628/629, 665, 666, 669–P [5], 669–T [6], 669–O [7], 670–H [8] and 670–O [9], as a group.	584,006,690 square meters equivalent.
Sublevels in Group I	
619/620	13,796,359 square meters.
625/626/627/628/629.	17,952,321 square meters.
Within Group I Sub-group	
219	15,441,054 square meters.
Group II	
237, 239, 330–332, 333/334/335, 336, 338/339, 340–345, 347/348, 349, 350/650, 351, 352/652, 353, 354, 359–C/659–C [10], 359–H/659–H [11], 359–O [12], 431–444, 445/446, 447/448, 459, 630–632, 633/634/635, 636, 638/639, 640, 641–644, 645/646, 647/648, 649, 651, 653, 654, 659–S [13], 659–O [14], 831–844 and 846–859, as a group.	734,740,158 square meters equivalent.
Sublevels in Group II	
239	5,709,605 dozen.
331	529,664 dozen pairs.
336	124,542 dozen.
338/339	921,051 dozen.
340	1,220,256 dozen.
345	111,385 dozen.
347/348	1,454,317 dozen of which not more than 1,288,567 dozen shall be in Categories 347–W/348–W [15].
359–H/659–H	4,960,415 kilograms.
433	13,947 dozen.
443	51,442 numbers.
445/446	139,870 dozen.

Category	Twelve-month limit [1]
631	4,908,140 dozen pairs.
633/634/635	1,641,935 dozen of which not more than 944,179 dozen shall be in Categories 633/634 and not more than 858,578 dozen shall be in Category 635.
638/639	6,556,836 dozen.
640	947,353 dozen of which not more than 281,710 dozen shall be in Category 640–Y [16].
642	917,016 dozen.
647/648	5,411,981 dozen of which not more than 5,088,804 dozen shall be in Categories 647–W/648–W [17].
659–S	1,617,719 kilograms.
Group II Subgroup	
333/334/335, 341, 342, 350/650, 351, 447/448, 636, 641 and 651, as a group.	74,695,173 square meters equivalent.
Within Group II Subgroup	
342	147,095 dozen.
351	413,344 dozen.
447/448	20,514 dozen.
636	387,480 dozen.
651	421,245 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1994.

[2] Category 870; Category 369–L: only HTS numbers 4202.12.4000, 4202.12.8020, 4202.12.8060, 4202.92.1500, 4202.92.3015 and 4202.92.6090; Category 670–L: only HTS numbers 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3030 and 4202.92.9025.

[3] Category 369–S: only HTS number 6307.10.2005.

[4] Category 369–O: all HTS numbers except 4202.12.4000, 4202.12.8020, 4202.12.8060, 4202.92.1500, 4202.92.3015, 4202.92.6090 (Category 369–L); and 6307.10.2005 (Category 369–S).

[5] Category 669–P: only HTS numbers 6305.31.0010, 6305.31.0020 and 6305.39.0000.

[6] Category 669–T: only HTS numbers 6306.12.0000, 6306.19.0010 and 6306.22.9030.

[7] Category 669–O: all HTS numbers except 6305.31.0010, 6305.31.0020, 6305.39.0000 (Category 669–P); 6306.12.0000, 6306.19.0010 and 6306.22.9030 (Category 669–T).

[8] Category 670–H: only HTS numbers 4202.22.4030 and 4202.22.8050.

[9] Category 670–O: all HTS numbers except 4202.22.4030 4202.22.8050 (Category 670–H); 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3030 and 4202.92.9025 (Category 670–L).

[10] Category 359–C: only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010; Category 659–C: only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[11] Category 359–H: only HTS numbers 6505.90.1540 and 6505.90.2060; Category 659–H: only HTS numbers 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.7090 and 6505.90.8090.

[12] Category 359–O: all HTS numbers except 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010 (Category 359–C); 6505.90.1540 and 6505.90.2060 (Category 359–H).

[13] Category 659–S: only HTS numbers 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6211.11.1010, 6211.11.1020, 6211.12.1010 and 6211.12.1020.

[14] Category 659–O: all HTS numbers except 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010 (Category 659–C); 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.7090, 6505.90.8090 (Category 659–H); 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6211.11.1010, 6211.11.1020, 6211.12.1010 and 6211.12.1020 (Category 659–S).

[15] Category 347–W: only HTS numbers Category 347–W: only HTS numbers 6203.19.1020, 6203.19.9020, 6203.22.3020, 6203.22.3030, 6203.42.4005, 6203.42.4010, 6203.42.4015, 6203.42.4025, 6203.42.4035, 6203.42.4045, 6203.42.4050, 6203.42.4060, 6203.49.8020, 6210.40.9033, 6211.20.1520, 6211.20.3810 and 6211.32.0040; Category 348–W: only HTS numbers 6204.12.0030, 6204.19.8030, 6204.22.3040, 6204.22.3050, 6204.29.4034, 6204.62.3000, 6204.62.4005, 6204.62.4010, 6204.62.4020, 6204.62.4030, 6204.62.4040, 6204.62.4050, 6204.62.4055, 6204.62.4065, 6204.69.6010, 6204.69.9010, 6210.50.9060, 6211.20.1550, 6211.20.6810, 6211.42.0030 and 6217.90.9050.

[16] Category 640–Y: only HTS numbers 6205.30.2010, 6205.30.2020, 6205.30.2050 and 6205.30.2060.

[17] Category 647–W: only HTS numbers 6203.23.0060, 6203.23.0070, 6203.29.2030, 6203.29.2035, 6203.43.2500, 6203.43.3500, 6203.43.4010, 6203.43.4020, 6203.43.4030, 6203.43.4040, 6203.49.1500, 6203.49.2010, 6203.49.2030, 6203.49.2040, 6203.49.2060, 6203.49.8030, 6210.40.5030, 6211.20.1525, 6211.20.3820 and 6211.33.0030; Category 648–W: only HTS numbers 6204.23.0040, 6204.23.0045, 6204.29.2020, 6204.29.2025, 6204.29.4038, 6204.63.2000, 6204.63.3000, 6204.63.3510, 6204.63.3530, 6204.63.3532, 6204.63.3540, 6204.69.2510, 6204.69.2530, 6204.69.2540, 6204.69.2560, 6204.69.6030, 6204.69.9030, 6210.50.5035, 6211.20.1555, 6211.20.6820, 6211.43.0040 and 6217.90.9060.

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,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 95–24888 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DR–F

Adjustment of Import Limits for Certain Cotton, Wool and Man-Made Fiber Textile Products Produced or Manufactured in the People's Republic of China

October 2, 1995.

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

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

EFFECTIVE DATE: October 3, 1995.

FOR FURTHER INFORMATION CONTACT: Jennifer Aldrich, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–6703. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

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

The current limits for certain categories are being increased for swing.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 59 FR 65531, published on December 20, 1994). Also see 59 FR 65760, published on December 21, 1994.

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.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

October 2, 1995

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

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 16, 1994, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textile products, produced or manufactured in the People's Republic of China and exported during the twelve-month period which began on January 1, 1995 and extends through December 31, 1995.

Effective on October 3, 1995, you are directed to amend further the directive dated December 16, 1994 to increase the limits for the following categories, as provided under the terms of the bilateral agreement between the Governments of the United States and the People's Republic of China:

Category	Adjusted twelve-month limit [1]
Sublevels in Group I	
347/348	2,519,843 dozen.
351	510,711 dozen.
444	208,785 numbers.
447	80,759 dozen.
448	22,702 dozen.
634	582,335 dozen.
638/639	2,389,287 dozen.
670–L [2]	15,012,093 kilograms.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1994.

[2] Category 670–L: only HTS numbers 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3030 and 4202.92.9025.

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,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 95–24889 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DR–F

Adjustment of Import Restraint Limits for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Hong Kong

October 2, 1995.

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

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

EFFECTIVE DATE: October 5, 1995.

FOR FURTHER INFORMATION CONTACT: Janet Heinzen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

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

The current limits for certain categories are being adjusted, variously, for swing, carryover, carryforward, carryforward used and special shift.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 59 FR 65531, published on December 20, 1994). Also see 60 FR 17322, published on April 5, 1995.

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 Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing, but are designed to assist only in the implementation of certain of their provisions.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

October 2, 1995.

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

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on March 30, 1995, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Hong Kong and exported during the period beginning on January 1, 1995 and extending through December 31, 1995.

Effective on October 5, 1995, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing (ATC):

Category	Twelve-month restraint limit [1]
Group I	
200–229, 300–326, 360–369, 400–414, 464–469, 600–629 and 665–670, as a group.	222,982,007 square meters equivalent.
Sublevels in Group I	
218/225/317/326	69,876,410 square meters.
219	38,500,003 square meters.
611	6,070,044 square meters.
617	3,829,773 square meters.
Group I Subgroup	
200, 226/313, 314, 315, 369(1) and 604, as a group.	101,956,765 square meters equivalent.
Within Group I Subgroup	
200	331,933 kilograms.
226/313	69,060,738 square meters.
314	18,624,851 square meters.
315	9,208,191 square meters.
369(1) [2] (shoptowels).	756,727 kilograms.
604	227,849 kilograms.
Group II	
237, 239, 330–359, 431–459, 630–659, as a group.	834,279,015 square meters equivalent.
Sublevels in Group II	
237	1,113,316 dozen.
239	5,103,586 kilograms.
331	4,047,509 dozen pairs.
333/334	287,113 dozen.
335	338,356 dozen.
338/339 [3] (shirts and blouses other than tank tops and tops, knit).	2,842,218 dozen.
338/339(1) [4] (tank tops and knit tops).	2,160,700 dozen.
340	2,754,006 dozen.
345	439,742 dozen.

Category	Twelve-month restraint limit [1]
347/348	6,626,784 dozen of which not more than 6,536,784 dozen shall be in Categories 347–W/348–W [5]; and not more than 4,988,758 dozen shall be in Category 348–W.
352	6,490,638 dozen.
359(1) [6] (coveralls, overalls and jumpsuits).	596,590 kilograms.
359(2) [7] (outer vests).	1,221,013 kilograms.
433	10,123 dozen.
434	10,867 dozen.
435	75,711 dozen.
436	98,608 dozen.
438	809,863 dozen.
442	89,794 dozen.
443	62,216 numbers.
444	40,658 numbers.
445/446	1,338,594 dozen.
447/448	67,318 dozen.
631	617,906 dozen pairs.
633/634/635	1,292,795 dozen of which not more than 484,990 dozen shall be in Categories 633/634 and not more than 991,817 dozen shall be in Category 635.
638/639	4,828,090 dozen.
641	834,274 dozen.
644	88,651 numbers.
645/646	1,323,287 dozen.
647	494,064 dozen.
648	1,145,353 dozen of which not more than 1,130,563 dozen shall be in Category 648–W [8].
649	791,378 dozen.
650	163,653 dozen.
652	4,714,475 dozen.
659(1) [9] (coveralls, overalls and jumpsuits).	641,161 kilograms.
659(2) [10] (swimsuits).	261,334 kilograms.
Group II Subgroup	
336, 341, 342, 350, 351, 636, 640, 642, and 651, as a group.	151,747,322 square meters equivalent.
Within Group II Subgroup	
336	218,970 dozen.
341	2,787,687 dozen.
342	533,307 dozen.
350	134,022 dozen.
351	1,190,853 dozen.
636	285,443 dozen.
640	912,325 dozen.
642	230,460 dozen.
651	291,393 dozen.
Group III	
831–844 and 847–859, as a group.	41,947,543 square meters equivalent.
Sublevels in Group III	
834	11,777 dozen.
835	110,557 dozen.
836	157,378 dozen.
840	656,722 dozen.
842	252,608 dozen.
847	352,683 dozen.
Limits not in a group	
845(1) [11] (sweaters made in Hong Kong).	1,125,219 dozen.
845(2) [12] (sweaters assembled in Hong Kong from knit to-shape components, knit elsewhere).	2,693,346 dozen.
846(1) [13] (sweaters made in Hong Kong).	181,959 dozen.
846(2) [14] (sweaters assembled in Hong Kong from knit-to-shape components, knit elsewhere).	438,451 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1994.

[2] Category 369(1): only HTS number 6307.10.2005.

[3] Categories 338/339: all HTS numbers except 6109.10.0018, 6109.10.0023, 6109.10.0060, 6109.10.0065, 6114.20.0005 and 6114.20.0010.

[4] Categories 338/339(1): only HTS numbers 6109.10.0018, 6109.10.0023, 6109.10.0060, 6109.10.0065, 6114.20.0005 and 6114.20.0010.

[5] Category 347–W: only HTS numbers 6203.19.1020, 6203.19.9020, 6203.22.3020, 6203.22.3030, 6203.42.4005, 6203.42.4010, 6203.42.4015, 6203.42.4025, 6203.42.4035, 6203.42.4045, 6203.42.4050, 6203.42.4060, 6203.49.8020, 6210.40.9033, 6211.20.1520, 6211.20.3810 and 6211.32.0040; Category 348–W: only HTS numbers 6204.12.0030, 6204.19.8030, 6204.22.3040, 6204.22.3050, 6204.29.4034, 6204.62.3000, 6204.62.4005, 6204.62.4010, 6204.62.4020, 6204.62.4030, 6204.62.4040, 6204.62.4050, 6204.62.4055, 6204.62.4065, 6204.69.6010, 6204.69.9010, 6210.50.9060, 6211.20.1550, 6211.20.6810, 6211.42.0030 and 6217.90.9050.

[6] Category 359(1): only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010.

[7] Category 359(2): only HTS numbers 6103.19.2030, 6103.19.9030, 6104.12.0040, 6104.19.8040, 6110.20.1022, 6110.20.1024, 6110.20.2030, 6110.20.2035, 6110.90.9044, 6110.90.9046, 6201.92.2010, 6202.92.2020, 6203.19.1030, 6203.19.9030, 6204.12.0040, 6204.19.8040, 6211.32.0070 and 6211.42.0070.

[8] Category 648–W: only HTS numbers 6204.23.0040, 6204.23.0045, 6204.29.2020, 6204.29.2025, 6204.29.4038, 6204.63.2000, 6204.63.3000, 6204.63.3510, 6204.63.3530, 6204.63.3532, 6204.63.3540, 6204.69.2510, 6204.69.2530, 6204.69.2540, 6204.69.2560, 6204.69.6030, 6204.69.9030, 6210.50.5035, 6211.20.1555, 6211.20.6820, 6211.43.0040 and 6217.90.9060.

[9] Category 659(1): only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[10] Category 659(2): only HTS numbers 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6211.11.1010, 6211.11.1020, 6211.12.1010 and 6211.12.1020.

[11] Category 845(1): only HTS numbers 6103.29.2074, 6104.29.2079, 6110.90.9024, 6110.90.9042 and 6117.90.9015.

[12] Category 845(2): only HTS numbers 6103.29.2070, 6104.29.2077, 6110.90.9022 and 6110.90.9040.

[13] Category 846(1): only HTS numbers 6103.29.2068, 6104.29.2075, 6110.90.9020 and 6110.90.9038.

[14] Category 846(2): only HTS numbers 6103.29.2066, 6104.29.2073, 6110.90.9018 and 6110.90.9036.

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

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 95–24890 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DR–F

Adjustment of Import Limits for Certain Cotton, Wool and Man-Made Fiber Textile Products Produced of Manufactured in Thailand

October 2, 1995.

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

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

EFFECTIVE DATE: October 3, 1995.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of of each Customs port or call (202) 927–6717. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

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

The current limits for certain categories are being adjusted, variously, for swing, carryforward and carryforward used.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 59 FR 65531, published on December 20, 1994). Also see 60 FR 17337, published on April 5, 1995.

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 Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing, but are designed to assist only in the implementation of certain of their provisions.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

October 2, 1995.

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

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on March 30, 1995, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Thailand and exported during the twelve-month period which began on January 1, 1995 and extends through December 31, 1995.

Effective on October 3, 1995, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
Levels in Group I	
604	640,158 kilograms of which not more than 382,173 kilograms shall be in Category 604–A [2].
607	2,499,033 kilograms.
Group II	
237, 330–359, 431–459, 630–659 and 831–859, as a group.	230,915,562 square meters equivalent.
Sublevels in Group II	
335/635/835	390,953 dozen.
338/339	2,020,547 dozen.
442	22,167 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1994.

[2] Category 604–A: only HTS number 5509.32.0000.

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,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementatin of Textile Agreements.

[FR Doc. 95–24891 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DR–F

Adjustment of an Import Limit for Certain Cotton Textile Products Produced or Manufactured in the People's Republic of China

October 2, 1995.

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

ACTION: Issuing a directive to the Commissioner of Customs increasing a limit.

EFFECTIVE DATE: October 12, 1995.

FOR FURTHER INFORMATION CONTACT: Jennifer Aldrich, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of this limit, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–6703. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

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

The current limit for Category 314 is being increased for swing. As a result, the limit for Category 314, which is currently filled, will re-open.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 59 FR 65531, published on December 20, 1994). Also see 59 FR 65760, published on December 21, 1994.

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.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

October 2, 1995.

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

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 16, 1994, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textile products, produced or manufactured in the People's Republic of China and exported during the twelve-month period which began on January 1, 1995 and extends through December 31, 1995.

Effective on October 12, 1995, you are directed to amend further the directive dated December 16, 1994 to increase the limit for Category 314 to 47,346,244 square meters [1], as provided under the terms of the bilateral agreement between the Governments of the United States and the People's Republic of China.

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

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 95–24892 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–DR–F

[1] The limit has not been adjusted to account for any imports exported after December 31, 1994.

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List paper fasteners to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: November 6, 1995.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403,

1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: On June 30, 1995, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (60 F.R. 34235) of proposed addition to the Procurement List.

Comments were received from the current contractor for the fasteners. The contractor conceded that Government sales of the fasteners comprised a very small portion of its total sales. However, it felt the loss of sales would be significant because it would be a substantial minority of its total sales of the specific items involved, and a somewhat smaller minority of the sales of its office products division. The contractor also noted the impact of declining business, industry consolidation, and diminishing general small business set-asides of Government buys, as opposed to set-asides restricted to special groups such as minority contractors. The contractor objected to the Committee having added other fasteners to the Procurement List in 1994 without giving it notice. Finally, the contractor noted that it had provided work to local organizations employing people with disabilities over the years.

The Committee looks at total sales in judging the impact of a Procurement List addition on a contractor because its concern is with the overall viability of the corporation. The contractor has conceded that the impact of this addition is small when viewed in this light, even when the cumulative effect of last year's addition is taken into account. The contractor also noted that industry consolidation by itself will likely lead to closing of its domestic office products plant. Declining business is a fact of life for many office products producers, including those participating in the Committee's program which have been hit by the effects of Government downsizing. The decline in general small business set-asides is probably also related to Government downsizing. In light of all these facts, it is unlikely that these Procurement List additions are the cause of the problems which the contractor foresees.

The Committee is required by law to follow an administrative process which includes notice in the Federal Register when it adds items to the Procurement List. This notice is considered legally sufficient for all affected parties. The Committee wrote to the contractor this year, but not last year, because it was unable to obtain current sales data on the contractor from other sources.

The Committee applauds the contractor for giving work to people with disabilities. However, the contractor is free to discontinue this work for business or other reasons, such as the union restrictions on layoffs which limited the amount of work given to these agencies in the past year. In contrast, the jobs created by the Committee's program are not subject to being discontinued for such reasons.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities, fair market price, and impact of the addition on the current or most recent contractors, the Committee has determined that the commodities listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

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

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities.

3. The action will result in authorizing small entities to furnish the commodities to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities proposed for addition to the Procurement List.

Accordingly, the following commodities are hereby added to the Procurement List:

Fastener, Paper

7510–00–205–0806
7510–00–235–6046
7510–00–235–6049
7510–00–235–6068
7510–00–244–1169
7510–00–455–7339

This action does not affect current contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 95–24937 Filed 10–5–95; 8:45 am]

BILLING CODE 6820–33–M

Procurement List Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to the Procurement List.

SUMMARY: This action adds to the Procurement List a commodity to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: November 6, 1995.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: On August 11, 1995, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (60 F.R. 43126) of proposed addition to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodity, fair market price, and impact of the addition on the current or most recent contractors, 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 51–2.4. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodity.

3. The action will result in authorizing small entities to furnish the commodity to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity proposed for addition to the Procurement List.

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

Bag, Plastic, General Purpose

8105–00–579–8451

This action does not affect current contracts awarded prior to the effective

date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 95–24936 Filed 10–5–95; 8:45 am]

BILLING CODE 6820–33–M

Procurement List; Proposed Additions and Deletion

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletion from Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities, military resale commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete a commodity previously furnished by such agencies.

COMMENTS MUST BE RECEIVED ON OR BEFORE: November 6, 1995.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities, military resale commodities and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

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

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities, military resale commodities and services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities, military resale commodities and services.

3. The action will result in authorizing small entities to furnish the commodities, military resale commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities, military resale commodities and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodities, military resale commodities and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Stamp, Custom, Pre-Inked
7520–01–381–8057
7520–01–381–8075
7520–01–381–8012
7520–01–381–8054
7520–01–381–8037
7520–01–381–8074
7520–01–381–8063
7520–01–352–7312
7520–01–368–7774
7520–01–381–7995
7520–01–381–7993
7520–01–381–8017
7520–01–357–6847
7520–01–357–6846
7510–01–381–8032
7510–01–368–3504
7510–01–381–8062
7510–01–381–8041
7510–01–381–8070
7510–01–381–8072
7520–01–NIB–1041 (1.625″H × 4″L)
7520–01–NIB–1042 (Signature Stamp)
7520–01–NIB–1043 (Logo Stamp)
7520–01–NIB–1044 (Signature Stamp)

NPA: The Lighthouse for the Blind, Inc. Seattle, Washington

Military Resale Commodities

Pillow, Fiber Fill
M.R. 764
M.R. 765
M.R. 766
NPA: Georgia Industries for the Blind, Bainbridge, Georgia

Services

Janitorial/Custodial
Centers for Disease Control and Prevention
Atlanta, Georgia
NPA: Goodwill Industries of Atlanta, Inc., Atlanta, Georgia

Mailroom Operation
Internal Revenue Services
300 North Los Angeles Street
Los Angeles, California
NPA: Elwyn, Inc., Elwyn, Pennsylvania at its facility in Fountain Valley, CA

Deletion

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

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action does not appear to have a severe economic impact on future contractors for the commodity.

3. The action will result in authorizing small entities to furnish the commodity to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity proposed for deletion from the Procurement List.

The following commodity has been proposed for deletion from the Procurement List:

Water Bag, Nylon Duck
8465–01–310–1259

Beverly L. Milkman,

Executive Director.

[FR Doc. 95–24935 Filed 10–5–95; 8:45 am]

BILLING CODE 6820–33–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Resources Group, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested person are invited to submit comments on or before December 5, 1995.

ADDRESSES: Written comments and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, DC 20202–4651, or should

be electronic mailed to the internet address #FIRB@ed.gov, or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Department of Education (ED) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (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 of the Information Resources Group, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. 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) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department, (2) will this information be processed and used in a timely manner, (3) is the estimate of burden accurate, (4) how might the Department enhance the quality, utility, and clarity of the information to be collected, and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: October 2, 1995.

Gloria Parker,

Director, Information Resources Group.

Office of Postsecondary Education

Type of Review: Reinstatement.

Title: Reporting and Recordkeeping Requirement for Douglas School & Stafford/Plus Loans.

Frequency: Annually.

Affected Public: Individual or households; State, Local or Tribal Government.

Reporting Burden:
Respondes: 4308.
Burden Hours: 1077.

Recordkeeping Burden:
Recordkeepers: 0.
Burden Hours: 0.

Abstract: Collection of State proposals for Targeted Teacher Deferment/Teacher Shortage Areas, of the Higher Education Act of 1965, as amended by the Higher Education Amendments of 1986.

Office of Educational Research and Improvement

Type of Review: New.

Title: Development of Measures of Elementary School Organization and Educational Processes: School Survey.

Frequency: One time.

Affected Public: Not for profit institutions.

Reporting Burden:
Responses: 300.
Burden Hours: 75.

Recordkeeping Burden:
Recordkeepers: 0.
Burden Hours: 0.

Abstract: This Study is the full-scale pilot test of the proposed data collection procedures and instrument for an effort to develop better measures of elementary school characteristics and processes that will be comparable with those of other countries. The survey was developed by the Indicators of Educational Systems Project in cooperation with the Organization for Economic Cooperation and Development (OECD) with support of the National Center for Education Statistics. Data will be collected on such topics as the stability of the school's staff, aspects of school leadership, cooperation among teachers, student evaluation practices, achievement orientation, and parent involvement.

[FR Doc. 95–24855 Filed 10–5–95; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Environmental Management Site Specific Advisory Board, Kirtland Area Office (Sandia); Meeting

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Kirtland Area Office (Sandia).

DATES: Wednesday, October 18, 1995: 6:50 pm–10:00 pm (Mountain Daylight Time).

ADDRESSES: Indian Pueblo Cultural Center, 2401 12th St. NW, Albuquerque, NM.

FOR FURTHER INFORMATION CONTACT: Mike Zamorski, Acting Manager, Department of Energy Kirtland Area Office, P.O. Box 5400, Albuquerque, NM 87185 (505) 845–4094.

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

6:45 pm Public Comment Period
7:00 pm Meeting Overview;
Nomination Committee Report;
Budget/Planning Committee Report;
New/Other Business
9:50 pm Public Comment
10:00 pm Adjourn

A final agenda will be available at the meeting Wednesday, October 18, 1995.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Mike Zamorski's office at the address or telephone number listed above.

Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments. This notice is being published less than 15 days before the date of the meeting due to programmatic issues that had to be resolved prior to publication.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday-Friday, except Federal holidays. Minutes will also be available by writing to Mike Zamorski, Department of Energy Kirtland Area Office, P.O. Box 5400,

Albuquerque, NM 87185, or by calling (505) 845–4094.

Issued at Washington, DC on October 2, 1995.

Rachel M. Samuel,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 95–24942 Filed 10–5–95; 8:45 am]

BILLING CODE 6450–01–P

Environmental Management Site-Specific Advisory Board, Oak Ridge; Meeting

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge.

DATES: Wednesday, October 25, 1995: 6:00 pm–9:00 pm.

ADDRESSES: Oak Ridge Mall Community Room, Oak Ridge, Tennessee.

FOR FURTHER INFORMATION CONTACT: Sandy Perkins, Site-Specific Advisory Board Coordinator, Department of Energy, Oak Ridge Operations Office, 105 Broadway, Oak Ridge, TN 37830, (423) 576–1590.

SUPPLEMENTARY INFORMATION: Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

October Meeting Topics

Topics to be discussed will be a mix of organizational issues as well as environmental management issues. The first half of the meeting will be a presentation given on the Environmental Restoration Program's prioritization system. The second half of the meeting will be devoted to organizational issues involving the formalization of the Board, i.e., draft operational procedures, the selection process for a chair, and any special training needs for the Board members.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Sandy Perkins' office at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be available at the Department of Energy's Information Resource Center at 105 Broadway, Oak Ridge, TN between 8:30 am and 5:00 pm on Monday, Wednesday, and Friday; 8:30 am and 7:00 pm on Tuesday and Thursday; and 9:00 am and 1:00 pm on Saturday, or by writing to Sandy Perkins, Department of Energy, Oak Ridge Operations Office, 105 Broadway, Oak Ridge, TN 37830, or by calling her at (423) 576–1590.

Issued at Washington, DC on October 2, 1995.

Rachel M. Samuel,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 95–24943 Filed 10–5–95; 8:45 am]

BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

[Docket No. CP95–783–000]

Colorado Interstate Gas Company; Notice of Application

October 2, 1995.

Take notice that on September 27, 1995, Colorado Interstate Gas Company (CIG), P.O. Box 1087, Colorado Springs, CO 80944, filed in Docket No. CP95–783–000 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon, by sale to Williams Gas Processing—Wamsutter Company, certain natural gas facilities in Sweetwater and Carbon Counties, Wyoming, and the services rendered thereby, all as more fully set forth in the application on file with the Commission and open to public inspection.

CIG states that the facilities to be abandoned are part of its North Wamsutter and Echo Springs gathering systems. CIG also states that the facilities to be abandoned consist of 17 miles of 8-inch, 3.5 miles of 6-inch and 1.1 miles of 4-inch lines as well as taps and facilities appurtenant thereto.

CIG states that the facilities will be sold at their net book value at the time of the sale. CIG also states that the net book value of the facilities on November 30, 1994 was $342,923.

In addition, CIG requests that the Commission state that the subject facilities will perform a non-jurisdictional gathering function when transferred.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 23, 1995, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a notion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for CIG to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 95–24857 Filed 10–5–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MG95–6–001]

Young Gas Storage Co., Ltd.; Notice of Filing

October 2, 1995.

Take notice that on September 1, 1995, Young Gas Storage Co., Ltd. (Young) filed revised standards of conduct to reflect a change in the ownership structure of Young and to comply with the Commission's August 2, 1995 order directing Young to revise its standards of conduct with respect to Standard I, 18 CFR 161.3(i). 72 FERC 61,141.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C., 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All such motions to intervene or protest should be filed on or before October 17, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 95–24858 Filed 10–5–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MT95–19–000]

Transcontinental Gas Pipe Line Corporation; Notice of Proposed Changes in FERC Gas Tariff

October 2, 1995.

Take notice that on September 26, 1995, Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing to become part of its FERC Gas Tariff, Third Revised Volume No. 1, certain revised tariff sheets which tariff sheets are enumerated in Appendix A attached to the filing. Such tariff sheets are proposed to be effective November 1, 1995.

Transco states that the purpose of the instant filing is to revise currently effective tariff provisions to comport with the requirements of Order Nos. 566 and 566–A. On April 13, 1995, the Commission issued its order on the January 31 Filing (April 13 Order). In the April 13 Order, the Commission rejected Second Revised Sheet No. 166 and First Revised Sheet No. 232 without prejudice to Transco resubmitting such rejected sheets to remove the language that requires shippers to disclose an end user unless the end user is a local distribution company, an interstate or intrastate pipeline.

Transco states that it is refiling Sheet Nos. 166 and 232 with the incorrect language deleted. Additionally, Transco has found similar language on Sheet No. 177 of Rate Schedule IT and is also filing this sheet to remove the incorrect language.

Transco states that it is serving copies of the instant filing to its customers, State Commissions and other interested parties.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E. Washington D.C. 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before October 10, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95–24859 Filed 10–5–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. PR95–7–000]

Tekas Corporation; Notice of Informal Settlement Conference

October 2, 1995.

Take notice that an informal settlement conference in the above-captioned proceeding will be held on Friday, October 13, 1995, at 10:00 a.m. in a room to be designated at the offices of the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426.

Attendance will be limited to the parties and staff. For additional information, please contact Michael J. Ahern at (202) 208–0527.

Lois D. Cashell,

Secretary.

[FR Doc. 95–24860 Filed 10–5–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM96–4–23–000]

Eastern Shore Natural Gas Company; Proposed Changes in FERC Gas Tariff

October 2, 1995.

Take notice that on September 27, 1995 Eastern Shore Natural Gas Company (ESNG) tendered for filing certain revised tariff sheets included in Appendices A and B attached to the filing. Such revised tariff sheets bear proposed effective dates as indicated therein.

ESNG states that the purpose of the instant filing is to track storage rate changes atttributable to (1) storage service purchased from Columbia Gas Transmission (Columbia) under its Rate Schedules FSS and SST, the cost of which are included in the rates and charges payable under ESNG's Rate Schedules CWS–1 and CFSS–1, respectively, and (2) storage service purchased from Transcontinental Gas Pipe Line Corporation (Transco) under its GSS and LSS Rate Schedules, the costs of which are included in the rates and charges payable under ESNG's Rate Schedules GSS–1 and LSS–1, respectively. This tracking filing is being made pursuant to Section of the General Terms and Conditions of ESNG's FERC Gas Tariff First Revised Volume No. 1. ESNG states that Appendices C and D attached to the filing contain the rate changes and details regarding the computation of the revised CWS–1, CFSS–1, GSS–1, and LSS–1 rates, respectively.

ESNG states that copies of the filing have been served upon its jurisdictional customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rule 211 and Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR Section 385.211 and Section 385.214). All such motions or protests shall be filed on or before October 10, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 95–24861 Filed 10–5–95; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5313–3]

Agency Information Collection Activities up for Renewal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) listed below is coming up for renewal. Before submitting the renewal package to the Office of Management and Budget (OMB), EPA is soliciting comments on specific aspects of the collection as described below.

DATES: Comments must be submitted on or before December 5, 1995.

ADDRESSES: Office of Wetlands, Oceans, and Watersheds (4503F), 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Barry Burgan, National 305(b) Coordinator, telephone: (202) 260–7060; facsimile: (202) 260–1977; email: burgan.barry@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Affected entities: Entities affected by this action are the 50 States, the District of Columbia, five Territories (Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands). Four Interstate River Basin Commissions and five Indian Tribes or Tribal Groups also sent data to EPA during the period covered by the current ICR. The SIC code for respondents is 9511 (Administration of Environmental Quality.

Programs: Air and Water Resources and Solid Waste Management).

Title: National Water Quality Inventory Reports (Clean Water Act Sections 305(b), 303(d), and 314(a)). OMB Control Number 2040–0071. Expiration date: February 29, 1996.

Abstract: Section 305(b)(1) of the Clean Water Act (Pub. L. 92–500, 33 U.S.C 1251 *et seq.*; most recently amended in 1987 by Pub. L. 100–4) requires each State to prepare and submit a biennial water quality assessment report to the EPA Administrator. Regulations for water quality monitoring, planning, management and reporting are found in 40 CFR part 130. Each 305(b) report includes such information as a description of the quality of waters of the State; an analysis of the extent to which these waters provide for the protection and propagation of a balanced population of shellfish, fish, and wildlife, and allow recreational activities in and on the water; recommendations for additional action necessary to achieve such uses; an estimate of the environmental impact and economic and social costs as well as the economic and social benefits of such achievement; and a description of the nature and extent of nonpoint sources of pollutants and recommendations as to programs needed to control each category of such sources.

Under CWA Section 314(a)(2), States must incorporate their Clean Lakes Report into the 305(b) reports. Clean Lakes Reports include an identification and classification according to trophic condition of all publicly owned lakes; a description of the methods to control sources of pollution and restore these lakes; methods to mitigate the harmful effects of high acidity; a list and description of publicly owned lakes for which uses are known to be impaired; and an assessment of the status and trends of water quality in lakes.

Section 303(d)(1) of the CWA requires States to identify and rank water-quality limited waters which will not meet State water quality standards after implementation of technology-based point source controls.

Reporting under Sections 305(b) and 314 is thus required of the 50 States. Reporting activities under Section 303(d) may be submitted as part of the 305(b) report or may be submitted under separate cover. Other respondents (Territories, River Basin Commissions, certain Indian Tribes or Tribal Groups) also prepare 305(b) reports to document the quality of their waters to EPA, Congress, and the public and, in some cases, to meet grant conditions.

The 305(b) reporting process is an essential component of the EPA water pollution control program. EPA's Office of Water uses the 305(b) reports as the principal information source for assessing nationwide water quality, progress made in maintaining and restoring water quality, and the extent of remaining water pollution problems. EPA prepares the National Water Quality Inventory Report to Congress and evaluates impacts of EPA's water pollution control programs with the information and data supplied in the State and Tribal 305(b) reports and the corresponding national database, the EPA Waterbody System. The Office of Water uses the Report to Congress to target persistent and emerging water quality problems with new initiatives and to improve or eliminate ineffective programs.

EPA uses the information submitted under Section 314 to evaluate the effectiveness of the Clean Lakes grant program. The Agency assembles national information on water quality trends in lakes eligible for Section 314 grants, initiation and completion of Clean Lakes Projects funded with 314 grants, and tangible results of lake restoration projects.

Under Section 303(d) EPA must review and approve or disapprove the State lists of water-quality limited waterbodies still requiring total maximum daily loads (TMDLs). Section 303(d) of the CWA establishes the TMDL process to provide for more stringent water-quality based controls when required Federal, State or local controls are inadequate to achieve State water quality standards. TMDLs encourage a holistic view of water quality problems considering all contributions and instream water quality and provide a method to allocate those contributions to meet water quality standards.

The next 305(b) reports and 303(d) lists are due to EPA in April 1996. Prior to each 305(b) reporting deadline, EPA publishes guidelines on the types of information requested of respondents in their 305(b) reports. The current edition is Guidelines for the Preparation of the 1996 State Water Quality Assessments (305(b) Reports), EPA 841–B–95–001, May 1995 (see contact information above).

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are displayed in 40 CFR Part 9. This ICR renewal does not involve third-party and public disclosures not previously reviewed and approved by OMB.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Burden Statement: The existing burden estimate for all reporting and

recordkeeping (from the currently approved ICR) was 256,654 burden hours per year. This estimate was based on 58 respondents and a biennial response frequency, and was equivalent to an average of 8,850 burden hours per biennial response. This estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. EPA intends to reduce the burden in the future by reducing the frequency for submitting the actual 305(b) reports to 5 years with annual electronic reporting on core elements for the geographic areas covered in that year.

Send comments regarding these matters, or any other aspect of the information collection, including suggestions for reducing the burden, to the address listed above.

Dated: September 29, 1995.

Robert H. Wayland III,

Director, Office of Wetlands, Oceans and Watersheds.

[FR Doc. 95–24878 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–U

[ER–FRL–5229–4]

Environmental Impact Statements; Notice of Availability

RESPONSIBLE AGENCY: Office of Federal Activities, General Information (202) 260–5076 OR (202) 260–5075. Weekly receipt of Environmental Impact Statements Filed September 25, 1995 Through September 29, 1995 Pursuant to 40 CFR 1506.9.

EIS No. 950442, DRAFT EIS, BOP, VA, Lee County, Virginia Federal Correctional Institution, Construction and Operation, Site Selection near the Town of Pennington Gap, Lee County, VA, Due: November 20, 1995, Contact: David S. Dorworth (202) 514–6470.

EIS No. 950443, DRAFT EIS, AFS, CA, Sequoia National Forest Trail System Plan, Implementation, Amendment to the Sequoia National Forest Land and Resource Management Plan, Fresno, Kern and Tulare Counties, CA, Due: January 05, 1996, Contact: Jim Whitefield (209) 784–1500.

EIS No. 950444, DRAFT EIS, BLM, OR, Bal'diyaka Interpretive Center Construction and Operation to Present the Natural History of Oregon's Southern Coast; the Cultural Heritage of the Coos, Lower Umpqua and Siuslaw Indians and Local US Coast Guard History, Implementation, Coos Bay District, Gregory Point, Coos County, OR, Due: December 06, 1995, Contact: Daryl Albiston (503) 756–0100.

EIS No. 950445, FINAL EIS, UAF, GU, Andersen Air Force Base (AFB) Solid Waste Management Facility, Construction, Island of Guam, GU, Due: November 06, 1995, Contact: Roy N. Tsutsui (671) 366–2101.

EIS No. 950446, FINAL EIS, DOE, WA, Columbia Wind Farm #1 Project, Construction and Operation of a 25 Megawatt (MW) Wind Power Project in the Columbia Hills Area, Conditional-Use-Permit, NPDES Permit and COE Section 404 Permit, Klickitat County, WA , Due: November 06, 1995, Contact: Kathy Fisher (503) 230–4375.

EIS No. 950447, DRAFT EIS, FHW, MO, MO–13 and MO–7 Highway/Freeway Improvements, MO–13 from US 24 in Lexington to Truman Reservoir south of Clinton and MO–7 in the immediate area of Clinton, Funding, Lafayette, Johnson and Henry Counties, MO, Due: November 20, 1995, Contact: Don Neumann (314) 636–7104.

EIS No. 950448, FINAL EIS, BIA, MT, Yellowstone Pipe Line Easement, Construction and Operation, Renewal of Right-of-Way (ROW) Grant for Easement across the Flathead Indian Reservation, Approval of Trust and Allotted Lands and COE Section 404 Permit, Missoula, Lake and Sanders Counties, MT, Due: November 06, 1995, Contact: Jim Beyer (406) 675–7200.

EIS No. 950449, DRAFT EIS, AFS, MT, Asarco Rock Creek Copper and Silver Mining Construction and Operation Project, Plan of Operations Approval, Special Use Permit(s), Road Use Permit, Mineral Material Permit, Timber Sale Contract and COE Section 404 Permit Issuance, Kootenai National Forest, Sanders County, MT, Due: November 20, 1995, Contact: Paul Kaiser (406) 293–6211.

EIS No. 950450, DRAFT EIS, BLM, OR, Tucker Hill Perlite Quarry Project, Implementation, Mining Plan of Operation, Approval, Town of Lakeview, Lake County, OR, Due: December 05, 1995, Contact: Ted Davis (503) 947–2177.

EIS No. 950451, DRAFT SUPPLEMENT, FTA, CA, Bay Area Rapid Transit District (BART) Transportation Improvements, San Francisco to San Francisco International Airport Extension, Alternative VI Aerial Design Option, Approval, Funding, COE Section 404 and Possible FHWA Encroachment Permits Issuance, San Mateo County, CA, Due: November 20, 1995, Contact: Robert Hom (415) 744–3115.

EIS No. 950452, FINAL EIS, NOA, Atlantic Coast Weakfish Fishery, Fishery Management Plan, Implementation, Weakfish Harvest Control in the Atlantic Ocean Exclusive Economic Zone (EEZ), off the New England, Mid-Atlantic and South Atlantic Coast, Due: November 06, 1995, Contact: Rolland Schmitten (301) 713–2239.

Amended Notices

EIS No. 950323, DRAFT SUPPLEMENT, FHW, ME, Sears Island Marine Dry Cargo Terminal and Access Road Construction, Updated and New Information concerning the Evaluation of the Alternatives, Funding and COE Section 10 and 404 Permits Issuance, Waldo County, ME, Due: October 13, 1995, Contact: Paul Lariviere (207) 622–8487. Published FR 08–18–95 - Review period extended.

EIS No. 950344, DRAFT EIS, FHW, CO, CO–82 Highway Transportation Project, Improvements to ''Entrance to Aspen'', Funding and COE Section 404 Permit, City of Aspen, Pitkin County, CO, Due: December 18, 1995, Contact: Ron Speral (303) 969–6737. Published FR 08–04–95 - Review period extended.

Dated: October 02, 1995.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 95–24993 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–U

[ER–FRL–5229–5]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared September 18, 1995 Through September 22, 1995 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) 260–5076.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 14, 1995 (60 FR 19047).

Draft EISs

ERP No. D–CGD–C50012–00 Rating EO2, Staten Island Bridges Program—Modernization and Capacity Enhancement Project, Construction and Operation, Funding, Right-of-Way Grant, COE Section 404 Permit and

NPDES Permit, Staten Island, NY and Elizabeth, NJ.

Summary: EPA expressed environmental objections to the project because of potential impacts to air quality and wetlands. EPA has also expressed concerns regarding the proposed project's impact to cultural resources. Accordingly, additional information must be provided in the final EIS to address these issues.

ERP No. D–DOE–J39022–00 Rating EC2, Programmatic EIS—Uranium Mill Tailings Remedial Action Ground Water Project, Clean up of 24 Mill Sites, Implementation.

Summary: EPA concurred with the preferred alternative and requested additional information be provided in the final EIS concerning passive remediation, groundwater, site characterization data, local land use authorities, pollution prevention and environmental justice.

ERP No. D–SFW–J64005–CO Rating EC2, Rocky Mountain Arsenal National Wildlife Refuge Establishment and Operation, Implementation, Adam County, CO.

Summary: EPA had environmental concerns about the lack of adequate analysis of the environmental effects of developing a Refuge on a hazardous waste site and the transition between Superfund site and Refuge.

ERP No. D–SFW–K99027–CA Rating LO, Stephens' Kangaroo Rat (SKR) Authorization for Incidental Take and Implementation of a Long-Term Habitat Conservation Plan, Western Riverside County, CA.

Summary: EPA expressed a lack of objections with the proposal.

ERP No. D–UAF–C11019–NY Rating EC2, Plattsburgh Air Force Base (AFB) Disposal and Reuse, Implementation, Clinton County, NY.

Summary: EPA expressed environmental concerns regarding the proposed project's impacts to wetlands, surface water quality, noise levels and indirect impacts. EPA requested additional information in the final EIS to address these issues.

ERP No. D–USN–G11030–TX Rating LO, Dallas Naval Air Station Disposal and Reuse, Implementation, City of Dallas, TX.

Summary: EPA had lack of environmental objections to this proposed action.

ERP No. DS–FHW–B40064–ME Rating EO2, Sears Island Marine Dry Cargo Terminal and Access Road Construction, Updated and New Information concerning the Evaluation of the Alternatives, Funding and COE Section 10 and 404 Permits Issuance, Waldo County, ME.

Summary: EPA expressed environmental objections to the proposed Sears Island dry cargo terminal, stating that the project would result in significant adverse impact to freshwater and marine habitats. EPA also determined that, as currently planned, the proposal terminal would not fit on the environmentally preferable site at Mack Point. EPA recommended that if the project were downsized or if the Sears Island proposal ultimately proved infeasible for environmental or cost reasons, the state should reconsider the Mack Point option. EPA has committed to working with the state to evaluate measures to offset the environmental impacts of the proposed project.

ERP No. DS–UAF–B11012–NH Rating EC2, Pease Air Force Base Disposal and Reuse, Updated Information, Implementation, Portsmouth, Newington, Greenland, Rye, Dover, Durham, Madburg and Rochester, NH and Kittery, Eliot and Berwicks, ME.

Summary: EPA's primary environmental concern is that the Air Force has not taken all reasonable steps to ensure that mitigation measures necessary to protect wetlands and air quality will be implemented. EPA urged the Air Force to incorporate into its ROD(s) firm commitments to implement the mitigation measures recommended in the draft supplement EIS.

Final EISs

ERP No. F–GSA–A80027–AZ Evo A. Deconcini Federal Building—United States Courthouse, Construction and Site Selection, Central Business Area (CBA), City of Tucson, Pima County, AZ.

Summary: EPA had no objection to the action.

Dated: October 3, 1995.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 95–24927 Filed 10–5–95; 8:45 am]

BILLING CODE 6560–50–U

FEDERAL MARITIME COMMISSION

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Notice of Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of Section 3, Public Law 89–777 (46 U.S.C. § 817(e)) and the Federal Maritime Commission's implementing regulations at 46 C.F.R. Part 540, as amended:

Hapag Lloyd Tours GmbH, Gustav-Deetjen-Allee 2–6, Bremen, D–28215, Germany

Vessel: BREMEN

Dated: October 2, 1995.

Joseph C. Polking,

Secretary.

[FR Doc. 95–24830 Filed 10–5–95; 8:45 am]

BILLING CODE 6730–01–M

Security for the Protection of the Public Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages; Notice of Issuance of Certificate (Casualty)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of Section 2, Public Law 89–777 (46 U.S.C. § 817(d)) and the Federal Maritime Commission's implementing regulations at 46 CFR Part 540, as amended:

Hapag Lloyd Tours GmbH, Hanseatic Cruises GmbH and Hapag Lloyd (Bahamas) Ltd., Gustav-Deetjen-Allee 2-6, Bremen, D–28215, Germany.

Vessel: BREMEN.

Dated: October 2, 1995.

Joseph C. Polking,

Secretary.

[FR Doc. 95–24827 Filed 10–5–95; 8:45 am]

BILLING CODE 6730–01–M

Ocean Freight Forwarder License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

Summit Trade Specialists (U.S.), Inc., dba Summit Transportation Services, 4621 Grumman Drive, Medforf, OR 97504, Officers: Dennis Elmer Schrank, President, Sidney Edward Gould, Secretary

Landstar Express America, Incorporated, 3411 Oak Lake

Boulevard, Charlotte, NC 28219, Officers: Neil A. DuJardin, President, Allen D. Watson, Executive Vice President

New K.S.A.I. Inc. dba K.S.A. America Inc., 9009 La Cienega Blvd., Inglewood, CA 90301, Officers: Susumu Kinoshita, Chairman, Kunihiro Iwahashi, President

International Cargo Services, Inc., 139 Mitchell Ave., Suite 277, So. San Francisco, CA 94080, Officers: Seymour A. Hills, President, Marcia A. Hills, Vice President

Dynamic International Cargo Corp., 4741 N.W. 72nd Ave., Miami, FL 33166, Officer: Ricardo F. Gallardo, President

Seacrest Associates, Inc. dba, Seacrest Container Lines, 5550 Merrick Road #304, Massapequa, NY 11758, Officers: Lothar Kammerer, President, Rose-Marie LeBel-Kemmerer, Vice President

Manfred J. Koberg, 4505 N.W. 72nd Ave., Miami, FL 33166, Sole Proprietor

By the Federal Maritime Commission.

Dated: October 2, 1995.

Joseph C. Polking,

Secretary.

[FR Doc. 95–24831 Filed 10–5–95; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Carlinville National Bank Shares, Inc.; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) 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 acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank 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 October 16, 1995.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Carlinville National Bank Shares, Inc., Carlinville, Illinois; to acquire Carlinville Tax Service, Carlinville, Illinois, and thereby engage in operating an income tax preparation subsidiary, pursuant to § 225.25(b)(21) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, October 2, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–24887 Filed 10–5–95; 8:45 am]

BILLING CODE 6210–01–F

Robert L. Oltman; 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 notice is available for immediate inspection at the Federal Reserve Bank indicated. Once the notice 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 indicated for the notice or to the offices of the Board of Governors. Comments must be received not later than October 20, 1995.

A. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. Robert L. Oltman, Pasadena, California; to retain a total of 11.01 percent of the voting shares of Marathon Bancorp, Los Angeles, California, and thereby indirectly retain shares of Marathon National Bank, Los Angeles, California.

Board of Governors of the Federal Reserve System, October 2, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–24886 Filed 10–5–95; 8:45 am]

BILLING CODE 6210–01–F

Dentel Bancorporation; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has 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)).

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 to the Reserve Bank indicated for that application 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.

Comments regarding this application must be received not later than October 31, 1995.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Dentel Bancorporation, Victor, Iowa; to acquire 100 percent of the voting shares of Corydon Bancorporation, Corydon, Iowa, and thereby indirectly aquire Corydon State Bank, Corydon, Iowa.

Board of Governors of the Federal Reserve System, October 2, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–24885 Filed 10–5–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Committee on Vital and Health Statistics Meeting

Pursuant to Pub. L. 92–463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS).

Times and Dates: 9 a.m.–5 p.m., October 24, 1995; 9 a.m.–5 p.m., October 25, 1995; 9 a.m.–5 p.m., October 26, 1995.

Place: Room 703A, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, D.C. 20201.

Status: Open.

Purpose: The purpose of this meeting is for the Committee to plan for the upcoming special meetings on the Core Data Elements Project; to discuss the Committee's work plan for the coming year; to consider reports from each NCVHS subcommittee; to receive reports from offices of the Department of Health and Human Services and department-wide Data Council; and to address new business as appropriate.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey building by non-government employees. Thus, persons without a government identification card should plan to arrive at the building each meeting day either between 8:30 and 9:00 a.m. or 12:30 and 1:00 p.m. so they can be escorted to the meeting. Entrance to the meeting at other times during the day cannot be assured.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050.

Dated: September 29, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–24898 Filed 10–5–95; 8:45 am]

BILLING CODE 4163–18–M

Health Care Financing Administration

[BPD–797–PN]

RIN 0938–AG65

Medicare Program; Limitations on Medicare Coverage of Cataract Surgery

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed notice.

SUMMARY: This notice announces the Medicare program's proposal to define medical necessity with respect to Medicare coverage of preoperative testing for cataracts, cataract surgery, and Nd:YAG capsulotomy.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 5, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–797–PN, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–797–PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of comments to: Allison Herron Eydt, HCFA Desk Officer, Office of Information and Regulatory Affairs, Room 10235, New Executive Office Building, Washington, DC 20503.

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

FOR FURTHER INFORMATION CONTACT: Karen McVearry, (410) 786–4643.

SUPPLEMENTARY INFORMATION:

I. Background

A. Medicare Program Description

The Medicare program was established by the Congress in 1965 through the enactment of title XVIII of the Social Security Act (the Act). This program provides payment for certain medical services and supplies for persons 65 years of age and over, certain disabled persons, and beneficiaries with end-stage renal disease.

While Medicare does cover many health care costs, the program was not designed to pay for every type of medical care for its beneficiaries. Section 1862(a)(1)(A) of the Act prohibits Medicare payment for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.

Longstanding Medicare policy has interpreted the term ''reasonable and necessary'' to mean that an item or service is safe and effective, not experimental or investigational, and generally accepted in the medical community. We have used various methods for seeking medical and scientific opinion in determining whether a health care technology is reasonable and necessary. These methods have included, at one time or another, the use of the Office of Health Technology Assessment (OHTA), a unit of the Agency for Health Care Policy and Research (AHCPR) within the Public Health Service (PHS), and various forms of consultation and liaison with national medical associations and groups along with carrier medical directors, our central office staff physicians, and PHS representatives.

In developing this proposal for a national coverage policy concerning preoperative testing, cataract removal surgery, and postoperative issues, we

carefully considered cataract practice guidelines developed by a private-sector panel of experts under the auspices of AHCPR (referenced in this notice as the ''Expert Panel'') as well as findings from several other studies discussed in this notice.

The following studies are those that we considered:

- Cataract Management Guideline Panel, *Cataract in Adults: Management of Functional Impairment,* Clinical Practice Guideline Number 4, Rockville, MD, U.S. Department of Health and Human Services, PHS, AHCPR, AHCPR Publication Number 93–0542, February 1993. (Throughout this notice, this study will be referred to as the *Clinical Practice Guideline*). In addition to the *Clinical Practice Guideline,* AHCPR also published as companion pieces a *Patient's Guide* (AHCPR Publication Number 93–0544) and *Management of Cataracts in Adults,* Quick Reference Guide for Clinicians Number 4 (AHCPR Publication Number 93–0543). (Copies of the guidelines may be obtained from the AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907; its toll free telephone number is 1–800–358–9295.)
- American College of Eye Surgeons, Outpatient Ophthalmic Surgery Society, Society for Excellence in Eye Care, and Society for Geriatric Ophthalmology, *Guidelines for Cataract Practice,* Bellevue, WA, McIntyre Eye Clinic and Surgical Center, February 1993. (Copies of the guidelines may be obtained from the McIntyre Eye Clinic and Surgical Center, 1920–116th Avenue NE., Bellevue, WA 98004; its toll free telephone number is 1–800–822–0199. Its fax number is 1–206–646–5914.)
- General Accounting Office (GAO), Program Evaluation and Methodology Division, *Cataract Surgery,* (GAO/PEMD–93–14 Cataract Surgery, B–239626, April 20, 1993. (Copies of the GAO study may be obtained from the following address: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. The telephone number is 1–202–512–1800. The fax number is 1–202–512–2250.)
- U.S. Department of Health and Human Services, Office of Inspector General (OIG), *Outpatient Surgery—Medical Necessity and Quality of Care* (OEI–09–88–01000, 1991). (Copies of the OIG study may be obtained from the following address: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. The telephone number is 1–202–512–1800. The fax number is 1–202–512–2250.)

B. Medicare Coverage of Cataract Surgery

A cataract is an opacification, or clouding, of the eye's lens that usually occurs as a part of the aging process. This condition affects about 50 percent of Americans between the ages of 65 and 75, and approximately 70 percent of people over 75. Not all cataracts require surgical removal. The presence of a cataract does not always produce a noticeable or functional impairment. Thus, cataract surgery is generally considered to be elective.

When cataract surgery is performed, the opacified lens is removed from the eye. Extracapsular extraction and phacoemulsification are cataract removal procedures. The extracapsular procedure is done by making an incision in the eye and removing the anterior portion of the capsule. In addition, the nucleus and lens cortex are also extracted, leaving behind the posterior capsule. Phacoemulsification cataract removal is a modification of the extracapsular procedure. In phacoemulsification, the nucleus of the cataract is fragmented by a probe through ultrasonic frequency while simultaneously aspirating the fragments from the eye. In most cases, an intraocular lens is then implanted in the treated eye. The Expert Panel reviewed medical literature and prepared guidelines based on that review, which revealed that these surgeries appear to be equally effective in restoring vision. Adequate data are not available to determine if one technique is more effective than the other in reducing or eliminating functional impairment due to the cataract.

Section 35–9 of the Medicare Coverage Issues Manual (HCFA–Pub. 6), ''Phacoemulsification Procedure—Cataract Extraction,'' states that phacoemulsification is an acceptable procedure for the removal of cataracts. Therefore, the Medicare program covers reasonable and necessary services furnished in connection with this procedure, as well as for extracapsular extractions.

Although Medicare presently does not have a national coverage policy that specifies the exact parameters for determining coverage of cataract surgery, there are guidelines for the coverage of presurgery cataract diagnostic evaluations in Medicare Coverage Issues Manual section 35–44, ''Use of Visual Tests Prior to and General Anesthesia in Cataract Surgery.'' Medicare currently covers one comprehensive eye examination and an A-scan and, if medically justified, a B-scan. (These scans use sonar to study structures that are not directly visible. They are used to determine the appropriate pseudophakic power of the intraocular lens. For most cases involving a simple cataract, a diagnostic ultrasound A-scan is used. For patients with a dense cataract, a diagnostic ultrasound B-scan may be used.) These ultrasound scans are billed and paid for separately from the comprehensive eye examination because they are separate procedures with their own Physicians' Current Procedural Terminology (CPT) codes. (Tests performed that have separate CPT codes are not included as part of the service reported under ''evaluation and management'' codes. Thus, A-scans and B-scans cannot be included in the payment for the comprehensive eye examination.)

Section 50–38 of the Medicare Coverage Issues Manual sets forth Medicare's current policy on endothelial cell photography. This test is used to determine the endothelial cell count, which is a predictor of success of ocular surgery or certain other ocular procedures. Section 50–38 states that this test may be covered in certain circumstances but that, if the test is performed as part of a presurgical examination for cataract surgery, coverage for the test is available only as part of the comprehensive eye examination. In this circumstance, therefore, separate payment is not made.

This notice proposes to continue this policy of limiting coverage of diagnostic testing performed before cataract surgery to a comprehensive eye examination, an A-scan, and, if medically necessary, a B-scan. Thus, Medicare's policy of not providing additional or separate coverage for other preoperative tests unless there is another diagnosis in addition to cataracts would be continued.

Currently, Medicare does not have a national coverage policy that specifically addresses the following tests:

- Contrast sensitivity testing, which is designed to measure the amount of contrast required to detect a specific stimulus.
- Glare testing, which attempts to reproduce the symptom of glare in cataract patients and to quantify the amount of visual impairment it causes by comparing acuity with and without a bright light source directed by the eye.
- Potential vision testing, which is designed to determine whether patients with obviously impaired vision have the potential to see well following cataract surgery.

C. Rationale for This Notice: Clinical Studies and Other Evaluations

In reviewing Medicare's cataract removal policy, we have reviewed the Expert Panel's *Clinical Practice Guideline* as well as the findings of the *Guidelines for Cataract Practice*, the GAO study, and the OIG study.

1. Findings From the Expert Panel

Through the sponsorship of AHCPR in PHS, the *Clinical Practice Guideline* was published in February 1993. In sponsoring development of this guideline, AHCPR convened an interdisciplinary panel of private-sector experts made up of ophthalmologists, nurses, optometrists, internists, a family physician, a psychiatrist, an anesthesiologist, a clinical social worker, and a patient representative. The panel first undertook an extensive and comprehensive interdisciplinary review of the field to define the existing knowledge base and to evaluate critically the assumptions and common wisdom in the field of cataract care. Next, the panel developed and initiated a peer review of the guideline drafts and field reviews with intended users in clinical sites. Finally, comments from these reviews were assessed and used in the development of the final guidelines.

The Expert Panel included the following findings concerning preoperative testing, cataract removal surgery, and postoperative issues in its guidelines.

a. Preoperative Testing. The *Clinical Practice Guideline* found inadequate scientific evidence to support the use of most preoperative tests in deciding whether cataract surgery is medically appropriate. These preoperative tests include contrast sensitivity testing, glare testing, potential vision testing, and specular photographic microscopy (referred to in this proposed notice as endothelial cell photography).

• Contrast Sensitivity Testing

The guidelines state that, at this time, there is inadequate evidence that contrast sensitivity testing provides information, beyond the information obtained through a patient's history and an ocular examination, that is useful for the determination of whether a patient would benefit from cataract surgery.

• Glare Testing

The report of the Expert Panel indicates that there is inadequate evidence that glare testing provides useful information beyond that found in a patient's history and an eye examination. This testing, however, may be useful for corroborating glare symptoms in a small percentage of cataract patients who complain of glare, yet measure good Snellen acuity (a standard method of measuring visual accuracy during an eye examination) in office testing. Even in these patients, a positive glare test does not determine whether surgery should be recommended.

• Potential Vision Testing

Regarding potential vision testing (PVT), the Expert Panel found that adequate evidence is lacking as to whether PVT can assist the ophthalmologist in predicting the outcome of cataract surgery.

• Endothelial Cell Photography

The Expert Panel found that there is currently no evidence or rationale to support the use of endothelial cell photography on all patients who have cataracts in order to predict the response of the cornea to cataract surgery.

• Other Preoperative Tests

Other preoperative tests were also reviewed by the Expert Panel. The panel concluded that the following tests are not indicated as part of the preoperative workup for cataract surgery unless specific circumstances justify them and unless the justification is documented in the patient's chart:

—Formal visual fields, which refers to the entire area that can be seen without shifting the gaze.
—Fluorescein angiography, which is a process in which dye is used to assess adequate circulation in the blood vessels of the eye.
—External photography, which is a photograph of the external portion of the eye and lens.
—Corneal pachymetry, which is a procedure that quantifies and monitors changes in the thickness of the central cornea.
—B-scan ultrasonography, defined earlier in this notice.
—Specialized color vision tests, which are done to determine the functional ability of the macula and optic nerve.
—Tonography, which records changes in intraocular pressure produced by the constant application of a known weight on the globe of the eye, reflecting the facility of outflow of the aqueous humor from the anterior chamber.
—Electrophysiologic tests, which test the organic functions of the eye by means of electrical current.

The Expert Panel's report indicates that most of the preoperative tests reviewed by the panel provide inadequate scientific evidence to support the need for surgery. Thus, the Expert Panel concluded that these tests do not predict the benefits a patient may experience from the surgery or negative outcomes of the surgery. The Expert Panel found inadequate evidence to support the use of these tests in most cases to determine the need for cataract removal surgery. The Expert Panel also found that ''special circumstances'' often necessitate the use of these preoperative tests.

b. Cataract Removal Surgery. The guidelines also found that surgery usually is not necessary solely because a cataract is present. The Expert Panel found that the decision to have cataract surgery should be based on several factors, such as a complete patient history and an ocular examination, and an evaluation of the effect of the cataract on the patient's visual and overall function, after assessing the patient's visual needs, and after a thorough consideration of the potential risks associated with the surgery. The Expert Panel believes that cataract surgery should be considered if—

• The individual is afflicted with visual disability that results in functional impairment, taking into special consideration the circumstances of the one-eyed patient;
• The individual suffers from a lens-induced disease (such as phacomorphic glaucoma or phacolytic glaucoma); or
• The individual has an ocular condition that requires cataract extraction in order to be adequately diagnosed or treated.

Functional impairment means that the cataract causes a reduction in visual function that significantly interferes with the person's ability to participate in everyday activities and infringes on the person's autonomy. Management of the cataract should be determined primarily on the basis of the patient's overall visual function and needs, a complete medical history, an eye examination, and the person's understanding of the risks and benefits of cataract surgery. The Expert Panel concluded that cataract surgery performed solely for improving vision should not be performed if the patient does not want surgery; if glasses or visual aids provide satisfactory functional vision; if the patient's lifestyle is not compromised; or if the patient is medically unfit for cataract removal surgery. Whether the patient's lifestyle is compromised because of the cataract is a decision made by the patient and reached through subjective criteria. In addition, the physician should assist in assessing the patient's visual needs as well as informing the patient of the potential risks associated with the cataract removal surgery. The

patient must decide whether the cataract infringes on his or her ability to carry out needed or desired activities. Therefore, it is the patient along with the physician who must determine whether the visual disability caused by the cataract is significant enough to warrant surgery.

The panel reviewed situations in which cataract surgery is indicated for both eyes. The panel concluded that indications for cataract removal surgery are the same as those for the first eye. Therefore, the same subjective and objective criteria used to determine the need for cataract removal in the first eye should also be used in the evaluation of the second eye. According to the panel, visual acuity, stereopsis, and visual field are all enhanced by binocular vision. These facts strongly support the potential benefit of cataract removal surgery on the second eye.

At this time, there appear to be no scientific data indicating the optimal time interval for surgically removing a cataract in the second eye. The panel strongly emphasized, however, that cataract removal surgery not be performed on both eyes at the same time. The panel warned that surgery on both eyes during the same procedure runs the risk of catastrophic consequences if there are unrecognized problems with unsterile instruments or materials used during the procedure.

In summary, the Expert Panel believes the goal of cataract treatment is to maintain or restore autonomy through appropriate treatment in order to remove the disability. In addition, the panel also asserts that the purpose of cataract surgery is to reduce and, ideally, alleviate functional impairment caused by the cataract. If a patient does not have to compromise everyday activities because of the cataract, the surgery is usually unnecessary. The panel considers surgery necessary only when the cataract has progressed to the point that the person's vision is functionally impaired to a level that infringes on the person's lifestyle.

c. Postoperative Issues. Opacification of the posterior, or back, lens capsule is a consequence of modern cataract surgery. As the cloudiness increases, the patient's vision is adversely affected. This opacification can lead to functional impairment. The most common technique for treating posterior capsular opacification (PCO) is Nd:YAG capsulotomy, also referred to as YAG or laser capsulotomy. This technique uses a laser to make a hole in the central part of the posterior lens to improve vision.

The Expert Panel lists indications for Nd:YAG capsulotomy in its *Clinical Practice Guideline* that include subjective, objective, and educational criteria. Nd:YAG capsulotomy is considered appropriate and justified when the ability to carry out needed and desired activities is impaired. The eye examination confirms the diagnosis of PCO and excludes other ocular causes of functional impairment, and also confirms that the patient has been educated about the risks and benefits of laser surgery to the posterior capsule.

The Expert Panel found no justification for Nd:YAG capsulotomy to be scheduled at the same time the patient is scheduled for cataract removal surgery, or when the cataract removal is performed. The Expert Panel noted that Nd:YAG capsulotomy should never be performed prophylactically because there is no predictable time at which this procedure may be necessary. The *Clinical Practice Guideline* reports that Nd:YAG capsulotomy is seldom needed before 3 months have elapsed following cataract surgery, and that Nd:YAG capsulotomy carries its own risks. Although PCO is common, it varies in severity and does not always necessitate surgery. It is rare that opacification is severe enough to require Nd:YAG capsulotomy within 3 months of cataract surgery, and it is uncommon within the first 6 months after cataract surgery. The Expert Panel asserts that less than 25 percent of those having cataract surgery have Nd:YAG capsulotomy done within 2 years of surgery. The Expert Panel found Nd:YAG capsulotomy to be a highly successful procedure. However, justification for Nd:YAG capsulotomy should be well documented in the patient's record.

2. Findings From the Guidelines for Cataract Practice

Another study on cataract removal was issued at approximately the same time that the AHCPR-sponsored *Clinical Practice Guideline* was published. The additional study is entitled *Guidelines for Cataract Practice* and was completed by a cooperative committee composed of members of the leadership of several clinical ophthalmic surgeon organizations. These guidelines represent a consensus of highly experienced surgeons who have been personally involved in the development of cataract surgical removal techniques, the treatment of patients, and the education of other ophthalmic surgeons.

a. Preoperative Testing. The *Guidelines for Cataract Practice*, like the *Clinical Practice Guideline*, states that before the decision to have cataract surgery is made, full information regarding the correct diagnosis of the cataract and the prognosis for return of visual function following the anticipated treatment must be obtained. The patient's medical history should be carefully evaluated including how the cataract presently affects the patient's ability to function normally. In other words, these guidelines support the Expert Panel's findings that functional impairment of the patient should be weighed heavily before deciding whether to have cataract removal surgery.

In addition, the *Guidelines for Cataract Practice* states that preoperative testing may be of some use in determining the presence of a cataract, as well as the presence of other ocular diseases. Several preoperative tests that are discussed in the Expert Panel's findings are also addressed in the *Guidelines for Cataract Practice.* Three specific tests are discussed in detail by both studies. These tests are contrast sensitivity testing, glare testing, and endothelial cell photography.

- *Contrast Sensitivity Testing*

Contrast sensitivity is a measure of the contrast level required for detection of a specified size of a test object. This test quantitatively reveals decreased perception of low contrast objects. Although the *Guidelines for Cataract Practice* indicates that contrast sensitivity has been shown to be an indication of the need of recognition of visual targets for those dealing with rapidly moving test targets, the Expert Panel's guidelines state only that there is inadequate evidence as to whether this test will indicate either the presence or severity of a cataract or a prognosis for improvement following cataract removal surgery.

- *Glare Testing*

Glare testing measures the effect of simulated glare on vision function. Disabling glare is often an indication that a cataract has developed. But, the *Guidelines for Cataract Practice* found that using glare testing as a diagnostic tool may be effective only if the patient complains of glare in situations when visual function would otherwise be considered satisfactory. If visual function is decreased in normal lighting conditions, glare testing adds little to the diagnostic evaluation. Although glare testing may indicate the presence of a cataract, the test does not measure the severity of the cataract or the prognosis for improvement after cataract surgery. Thus, this test does not show that cataract removal surgery is medically necessary.

• *Endothelial Cell Photography*

Endothelial cell photography may be done before an intraocular operation because the corneal endothelium is particularly sensitive to the trauma of the surgery. This test is used to measure and record the evaluation of corneal endothelial cells. Patients with a preoperative reduction of their endothelial cell density are unusually sensitive to the trauma of surgery and may not maintain adequate visual functions following surgery. The *Guidelines for Cataract Practice* found that endothelial cell photography is useful in these cases to predict unusual surgical risks because low endothelial cell density may not be accurately predicted by patient history or examination. However, the *Guidelines for Cataract Practice* also found that many patients of low endothelial cell density can be identified through the patient's medical history and clinical examination.

• *Other Tests*

In addition to contrast sensitivity, glare testing, and endothelial cell photography, the *Guidelines for Cataract Practice* discusses other preoperative tests. The *Guidelines for Cataract Practice* states that these additional tests may be of some use in the diagnosis and prognosis of cataract removal. The *Guidelines for Cataract Practice* suggests that patients with ocular diseases other than cataracts would benefit from additional preoperative testing because these tests would protect the patient from disappointing results if the cataract is not the major cause of visual impairment. Some of these additional tests are also discussed in AHCPR-sponsored *Clinical Practice Guideline*. In addition to the tests previously mentioned, both studies discuss B-scan ultrasonography, corneal pachymetry, the electrophysiological test, external photography, fluorescein angiography, formal visual fields, the specialized color vision test, and tonography.

b. Cataract Surgery. Regarding the treatment of cataracts, the findings from the *Guidelines for Cataract Practice* are similar to those in the Expert Panel's guidelines. The *Guidelines for Cataract Practice* agrees with the Expert Panel's guidelines, which state that the goal of cataract removal surgery for the purpose of functional rehabilitation is improvement of visual function. Surgery should be performed for the purpose of reducing or eliminating functional impairment caused by the cataract.

The *Guidelines for Cataract Practice* concurs with the Expert Panel's findings that surgery generally is not necessary solely because the cataract is present. Both guidelines list similar reasons why a patient may choose not to have surgery. These reasons include:

• The patient does not desire surgery.

• Glasses or visual aids provide functional vision satisfactory to the patient's needs and desires.

• The patient's lifestyle is not compromised.

• The patient is known to be medically unfit for safe surgical intervention.

The *Guidelines for Cataract Practice* generally supports the Expert Panel's findings regarding surgical removal of a cataract in the second eye. The guidelines concludes that surgery on the second eye is justified in order to restore binocular vision. In addition, the subjective and objective criteria used to determine the necessity of cataract removal for the first eye must also be fulfilled before performing the same procedure on the second eye.

While the *Guidelines for Cataract Practice* agrees that cataract removal generally should not be performed on both eyes during the same procedure, additional findings contend that some clinical circumstances may exist that would require consideration of operating on both eyes simultaneously. For example, a patient who has poor general health and multiple medical conditions may be a candidate for dual cataract removal because of the high risk involved in anesthetizing the patient twice. It is suggested that whenever possible, however, cataract removal surgery be performed on each eye separately and that sufficient time be allowed for the first eye to heal before the second cataract removal is performed.

The Expert Panel's guidelines and the *Guidelines for Cataract Practice* both agree that the decision to have cataract surgery should be left to the patient after all appropriate counseling has been provided.

c. Postoperative Issues. The *Guidelines for Cataract Practice*, like the Expert Panel's findings, indicates that PCO frequently occurs after cataract removal surgery. Nd:YAG laser capsulotomy was found to be the most commonly performed procedure to relieve PCO. Management of functional impairment due to PCO is similar to the management of the procedure that removes the cataract. Findings from the *Guidelines for Cataract Practice* also are consistent with the Expert Panel's guidelines that Nd:YAG capsulotomy should not be performed or scheduled at the same time cataract removal is performed. Both studies assert that routine or prophylactic posterior capsulotomy is not appropriate.

3. Findings from GAO

In April 1993, GAO issued a report on cataract surgery. GAO's findings support the Expert Panel's assertion that the mere presence of a cataract does not necessitate the surgical removal of the cataract. GAO set up a study to determine how many cataract surgeries were performed unnecessarily. GAO hypothesized that the four States (California, Massachusetts, Pennsylvania, and Texas) from their survey on eye symptoms and functional impairment before and after surgery were not unrepresentative of current practice and applied the permissive criterion that surgery is considered inappropriate if the patient reported no functional impairment. The study revealed that by using the criterion of functional impairment, 6 percent of the respondents' surgeries were inappropriate. GAO further calculated that every 1 percent of cataract surgeries represented approximately $34 million in expenditures for Medicare. Under this scenario, GAO concluded that Medicare spent $204 million in 1991 for inappropriate cataract surgery. This is a conservative estimate considering that, in that same year, 1.35 million cataract surgeries were performed for which the Medicare program alone spent $3.4 billion. GAO theorized that if the number of inappropriate surgeries could be reduced, Medicare would not only save a great deal of money, but the quality of care for individuals with cataracts would improve.

4. Findings from OIG

The OIG's study, *Outpatient Surgery—Medical Necessity and Quality of Care* (OEI–09–88–01000, 1991), found that high-volume ophthalmologists (those who earn at least $1 million annually) are more likely to perform medically unnecessary surgeries and provide poor or questionable care than non-high-volume ophthalmologists.

II. Provisions of the Proposed Notice

The findings from the Expert Panel regarding cataract surgery and postoperative issues are supported by information found in the *Guidelines for Cataract Practice*. The GAO study concluded that there are substantial numbers of inappropriate cataract surgeries, while the OIG study found that high-volume ophthalmologists are more likely to perform medically unnecessary surgeries and provide poor or questionable care than non-high-volume ophthalmologists.

After evaluating these findings, we are proposing to adopt the following policies:

• Medicare would maintain its policy of paying only for a comprehensive eye examination or brief/intermediate examination as well as an A-scan and, if medically necessary, a B-scan before cataract surgery if the patient's only diagnosis is cataracts. We believe coverage of the B-scan is justified because this is a necessary diagnostic test for a patient who has a dense cataract rather than a simple cataract, which can be tested with an A-scan.

Thus, Medicare would include payment for tests such as contrast sensitivity, glare testing, and potential vision testing in the payment for the comprehensive eye examination performed before cataract surgery if the patient's only diagnosis is cataracts. Additional or separate payment for these tests would not be allowed if the only diagnosis is cataracts. Also, when there is a diagnosis in addition to cataracts, we would require that the medical need for these tests be documented in the patient's medical record whenever they are performed.

• Medicare would cover cataract surgery only for individuals who desire the surgery; who are medically fit for the surgery; and whose lifestyle is compromised by functional impairment because of the cataract, as documented in the patient's medical record. Medicare would not consider cataract surgery reasonable and necessary if glasses could satisfactorily correct the condition; if the patient's lifestyle was not compromised; or, if surgery was performed solely because a cataract was present. Medicare would also cover cataract surgery for individuals who suffer from lens-induced disease and ocular conditions requiring clear media.

• The Expert Panel's guidelines strongly emphasized that clinical studies have revealed that there is the potential for great risk if cataract removal is performed on both eyes during the same procedure. As a result, the Expert Panel found that cataract removal be performed on each eye during separate procedures and sufficient time be allowed for the first eye to heal before cataract removal is performed on the second eye. If extraordinary medical circumstances exist in which it may be dangerous or life-threatening for the patient to undergo anesthesia twice, a single procedure may be considered. Medicare coverage extends to both sets of circumstances.

• Medicare would cover Nd:YAG capsulotomy only if this procedure is performed subsequent to cataract surgery and is found to be medically necessary. Namely, Nd:YAG capsulotomy would be covered when it is reasonable and medically necessary to remedy functional impairment due to opacification following cataract surgery, as documented in detail in the patient's record. Medicare would not cover Nd:YAG capsulotomy if this procedure is performed or scheduled concurrently with cataract removal surgery.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

• Whether the information collection is necessary and useful to carry out the proper functions of the agency;

• The accuracy of the agency's estimate of the information collection burden;

• The quality, utility, and clarity of the information to be collected; and

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements discussed below.

The information collection requirements concern written documentation in the patient's medical record of the necessity of cataract surgery. The record must state that the individual desires the surgery, is medically fit for the surgery, and the lifestyle of the individual is compromised by functional impairment because of the cataract; or, the individual suffers from lens-induced disease and ocular conditions requiring clear media. The information collection requirements also concern written documentation in the patient's medical record of the necessity of Nd:YAG capsulotomy. The record must state that this procedure is performed subsequent to cataract surgery and is found to be medically necessary to remedy a documented functional impairment because of opacification following cataract surgery. Physicians, specifically ophthalmologists, would provide the information. Public reporting burden for this collection of information is estimated to be 166,666 hours per year based on an average of 5 minutes per service for a total of approximately 2 million services furnished in 1994.

These reporting and recordkeeping requirements are not effective until they have been approved by OMB. A notice will be published in the Federal Register when approval is obtained.

Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to HCFA, OFHR, MPAS, C2–27–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850 and to the OMB official whose name appears in the **ADDRESSES** section of this preamble.

V. Regulatory Impact Analysis

A. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a notice would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all ophthalmologists, ambulatory surgical centers (ASCs), and hospitals are considered to be small entities.

We are preparing a regulatory impact analysis because we anticipate that a majority of the ophthalmologists who perform cataract surgery would be affected by recommendations contained in this notice. The following discussion describes what we know about the impact of this proposed notice on affected entities and is intended to fulfill the requirements of the RFA.

1. Background

The effect of a cataract on vision can range from minimal to catastrophic. In most cases, surgical removal of the obscured natural lens, usually combined with the insertion of an artificial lens implant, is the only treatment option available. In recent years, the vast majority of these operations have been performed either in a hospital outpatient department or in a Medicare-

certified ASC. The GAO report, *Cataract Surgery*, discussed earlier in this notice, mentions that the Medicare program paid for more than 1.8 million outpatient cataract surgeries in 1991. Our payment data indicate that these surgeries cost the Medicare program in excess of $3.4 billion.

The information in the GAO report, issued in April 1993, was based on a random sample survey of 1,964 Medicare patients living in four States who had undergone cataract surgery. Usable responses were obtained from 76 percent of the sample. About 75 percent of the responding Medicare patients reported one or more substantial functional impairments affecting their ability to drive, read, or watch television before their cataract surgery. If the criterion for surgery is that any level of problem with either symptoms or functions (even those the patient considers slight) is sufficient to warrant surgery, responses to the GAO survey show that few surgeries (2.5 percent) were inappropriate. If the criterion is functional impairment, then 6 percent of the respondents' surgeries could be considered inappropriate.

The GAO report stated that the data from the four States did not allow them to make generalizations regarding the likely levels of questionable cataract surgery in the nation as a whole. However, to get some sense of the financial importance reducing this surgery could have, GAO: (1) Hypothesized that the four States in the survey were not unrepresentative of current practice; (2) applied the permissive criterion that, for the surgery to be considered inappropriate, a patient must have reported no functional impairment; and (3) calculated that every 1 percent of cataract surgeries represented approximately $34 million in expenditures for the Medicare program as a whole. Under the outlined scenario, GAO reported that Medicare spent approximately $200 million in 1991 for inappropriate cataract surgery.

2. Effects on Expenditures

We believe that the provisions of this notice would facilitate savings. First, by reaffirming existing coverage for preoperative tests, we eliminate or reduce any confusion about this matter. Medicare would continue to pay for a comprehensive eye examination and an A-scan and, if medically necessary, a B-scan if the patient's only diagnosis is cataracts. Payment for additional preoperative tests would be considered as part of the payment for the comprehensive eye examination. Additional or separate payment would not be allowed for tests other than the comprehensive eye examination, A-scan, and, if medically necessary, a B-scan if the patient's only diagnosis is cataracts.

Second, we believe that savings would result from a reduction of unnecessary cataract-removal surgeries. We do not have our own estimate determining to what degree cataract surgery is performed inappropriately or the effect this notice would have on reducing inappropriate cataract surgery. However, the GAO report estimated that 6 percent of the respondents' surgeries could be considered inappropriate.

Medicare would cover cataract removal surgery only if specific indications for the surgery are fulfilled. The group that may be most affected by the inclusion of these indications would be high-volume ophthalmologists. In its 1991 report, as discussed earlier in this notice, OIG stated that high-volume ophthalmologists (those who earn at least $1 million annually) perform almost twice the rate of medically unnecessary surgery and questionable care as non-high-volume ophthalmologists.

Third, we believe there would be a decline overall in the number of Nd:YAG capsulotomies performed as a result of requiring physicians to document in the patient's medical record that the patient suffers from functional impairment due to PCO before performing or scheduling the surgery. Since we are proposing to redefine what constitutes medical necessity for Nd:YAG capsulotomy, we believe the frequency the procedure is performed prophylactically (sometimes within 3 months following cataract surgery) would be drastically reduced, resulting in additional savings.

We cannot estimate the value of any savings we anticipate as a result of this notice because we lack information. Savings would depend upon our ability to generate payment edits that would help us enforce the proposed coverage policy.

3. Effects on Providers

Cataract surgery performed to redress functional impairment due to cataract in the adult is the most common surgical procedure performed on Americans age 65 and over. As a result, cataract surgery is a significant item in the Medicare budget. The extent that ophthalmologists would be affected by this notice would depend upon the extent that they perform cataract surgery on Medicare beneficiaries that would not conform to the medical necessity criteria proposed in this notice. All ophthalmologists who treat Medicare beneficiaries, especially those who perform a high volume of cataract procedures, would be required to review their methods of evaluating patients before surgery. Also, ophthalmologists would be required to review their criteria for performing surgery to ensure that they perform surgery only on those Medicare patients who have a functional impairment resulting from the effect of the cataract that compromises the patient's lifestyle and for whom glasses do not satisfactorily correct the condition. Under the provisions of this notice, the ophthalmologists must document in the patient's record any impairment requiring cataract surgery.

Because the policies we are proposing reflect some of the findings stated in the guidelines, which were developed by an interdisciplinary private sector Expert Panel under the sponsorship of AHCPR, we anticipate that the guidelines would be acceptable to those physicians furnishing services to Medicare beneficiaries. Most ophthalmologists are already documenting to some extent the need for cataract surgery in patients' records; however, this notice would impose additional requirements on ophthalmologists. We believe that any decrease in the number of tests and procedures that would result due to a change in Medicare policy would primarily affect ophthalmologists performing a high volume of cataract-related procedures on Medicare beneficiaries. The GAO findings describe a situation in which Medicare expenditures could be reduced and the quality of services furnished by ophthalmologists could be enhanced at the same time.

In recent years, the vast majority of cataract surgery procedures have been performed either in a hospital outpatient department or in a free-standing ASC. Cataract procedures are performed approximately twice as often in a hospital outpatient department as in an ASC. A facility that specializes in eye procedures would be affected to a greater extent if the number of cataract surgery procedures is reduced than a facility that handles a wider range of surgical procedures.

B. Rural Hospital Impact Statement

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a notice may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of

a Metropolitan Statistical Area and has fewer than 50 beds.

This notice would have little direct effect on payments to rural hospitals since this rule would recommend coverage changes that would affect primarily ophthalmologists, ASCs, and hospital outpatient surgery departments. Very few small rural hospitals would have an outpatient surgery department.

We are not preparing an analysis for section 1102(b) of the Act since we have determined, and the Secretary certifies, that this notice would not result in a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Sections 1861 and 1862 of the Social Security Act (42 U.S.C. 1395x and 1395y))

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare Supplementary Medical Insurance)

Dated: May 7, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: June 30, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95–24835 Filed 10–5–95; 8:45 am]

BILLING CODE 4120–01–P

Office of the Secretary

Assistant Secretary for Management and Budget; Statement of Organization, Functions, and Delegations of Authority

Part A (Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (DHHS), Chapter AH ''Office of the Assistant Secretary for Personnel Administration,'' as last amended at 57 FR 7391; and Chapter AM ''Office of the Assistant Secretary for Management and Budget,'' as last amended at 57 FR 8334 is being amended. The reorganization will abolish the Office of the Assistant Secretary for Personnel Administration and transfer the remaining functions to the HHS Office of Management and Budget. It will also establish the Departmental Appeals Board as a component within the Office of the Secretary. The Specific amendments to Part A are:

I. Make the following changes to Chapter AA ''Office of the Secretary,'' paragraph AA.10 Organization: Delete the Office of the Assistant Secretary for Personnel Administration and insert the Departmental Appeals Board.

II. Under Chapter AH, beginning with paragraph Section AH.00 Mission delete the remaining functions within the Office of the Assistant Secretary for Personnel Administration in its entirety.

III. Make the following changes to Chapter AM:

A. Section AM.00 Mission. Delete in its entirety and replace with the following:

AM.00 Mission. The mission of the HHS Management and Budget Office is to provide advice and guidance to the Secretary on administrative, budget, financial management, equal employment opportunity, and personnel, and to provide for the direction and coordination of these activities throughout the Department.

B. Section AM.10 Organization. Delete in its entirety and replace with the following:

AM.10 Organization. The HHS Management and Budget Office is headed by the Assistant Secretary for Management and Budget (ASMB). The ASMB is the Departmental Chief Financial Officer (CFO), and reports to the Secretary. The ASMB also serves as the Director for Equal Employment Opportunity for the Department. The office consists of the following organizations:

Immediate Office (AM)
Office of Grants and Acquisition Management (AMG)
Office of Budget (AML)
Office of Information Resources Management (AMM)
Office of Finance (AMN)
Administrative Services Center (AMQ)
Office of Human Resources (AMP)

C. Section AM.20 Functions is amended to add paragraph G, Office of Human Resources.

G. Office of Human Resources (AMP) advises and supports the Secretary and the Assistant Secretary for Management and Budget/CFO in the development and assessment of human resource programs and personnel policies. In coordination with the Operating Divisions (OPDIVs), formulates HHS policies pertaining to employment, compensation, position classification, employee benefits, performance management, employee development, and employee and labor relations. On behalf of the Department's Director of Equal Employment Opportunity (EEO), adjudicates complaints of discrimination. Serves as Departmental liaison to central management agencies exercising jurisdiction over personnel and EEO matters.

D. Establish a new Chapter AMP. The Office of Human Resources.

AMP.00 Mission. The Office of Human Resources (OHR) Provides leadership in the planning and development of personnel policies and human resource programs that support and enhance the Department's mission. Provides technical assistance to the Operating Divisions (OPDIVs) in building the capacity to evaluate the effectiveness of their human resource programs and policies. Serves as the Departmental liaison to central management agencies on topics relating to EEO and personnel matters.

AMP.10 Organization. The Office of Human Resources (OHR), headed by a Deputy Assistant Secretary for Human Resources who reports to the Assistant Secretary for Management and Budget, consists of the following components:

Immediate Office (AMP)
Policy Coordination Staff (AMP–1)
Personnel Programs Group (AMP–2)
Equal Employment Opportunity Programs Group (AMP–3)

AMP.20 Function. 1. The Immediate Office of Human Resources (OHR), provides leadership to the development and assessment of the Department's human resources programs and policies. In coordination with the Operating Divisions, designs human resource programs that support and enhance the HHS missions. Provides technical assistance to the OPDIVs in building the capacity to evaluate the effectiveness of their human resource programs and policies, including the development of performance standards. On behalf of the Department's Director of Equal Employment Opportunity, adjudicates complaints of discrimination. Serves as Departmental liaison to central management agencies exercising jurisdiction over personnel and EEO matters.

2. Policy Coordination Staff. Provides a variety of program support services to the components of the Office of Human Resources and to the OPDIVs. Coordinates the design of the evaluation capabilities and systems for use by the OPDIVs in determining the effectiveness of their personnel and EEO programs. Analyzes workforce data and trends to support program evaluation and strategic planning efforts, both at the departmental and OPDIV levels. Coordinates the development, approval, and dissemination of Departmental human resource policies.

3. Personnel Programs Group. Provides leadership to the planning and development of personnel policies and programs that support and enhance the Department's mission. In coordination with the OPDIVs, formulates HHS policies pertaining to employment, compensation, position classification,

employee benefits, performance management, employee development, and employee and labor relations. Provides technical assistance to the OPDIVs in the proper application of Federal personnel laws, regulations, and policies. Provides strategic advice to the Deputy Assistant Secretary for Human Resources, the Assistant Secretary for Management and Budget, and the Secretary on those initiatives having major workforce implications. Promotes and supports OPDIV capacity building efforts, including innovative approaches to personnel program management. Serves as the Department's focal point for liaison on personnel and labor relations issues with the Office of Personnel Management, the General Accounting Office, the Merit Systems Protection Board, and the Federal Labor Relations Authority.

4. EEO Programs Group. Provides leadership to the planning and development of affirmative employment policies and programs that recognize and value the diversity of the Department's workforce and promote a workplace free of discrimination. Provides technical assistance and enabling tools to the OPDIVs in the design of innovative, effective affirmative employment programs. Keeps top HHS officials apprised of workforce demographics and recommends positive interventions as needed. Prepares, for the Director of Equal Employment Opportunity, final Departmental decisions on the merits of complaints of discrimination, and prepares proposed dispositions of complaints presenting conflicts of interest for OPDIV and STAFFDIV officials. Serves as the Department's focal point for liaison with the Office of Personnel Management, the Equal Employment Opportunity Commission, and the General Accounting Office on issues pertaining to affirmative employment and discrimination complaints.

IV. Retitle Chapter AH, as the ''Departmental Appeals Board,'' to read as follows:

A. Section AH.00 Mission. The Departmental Appeals Board is an independent office established pursuant to provisions of law, regulations, and Secretarial delegations to provide conflict resolution services through the U.S. Department of Health and Human Services. These services are basically of two types: (a) Adjudicatory hearings, appellate review of decisions of administrative law judges, arbitration, and similarly structured formal and informal reviews of contested decisions; and (b) alternative dispute resolution (ADR), including mediation and other consensual processes, and training related to ADR and conflict management.

B. Section AH.10 Organization. The Departmental Appeals Board, under the leadership of the Chair, who is supervised by the Deputy Secretary of the Department, includes:

A. The Immediate Office of the Departmental Appeals Board, which includes:

(1) The Chair;

(2) The Deputy Chair;

(3) The Director of Administration;

(4) The Director of Mediation Services;

(5) Board Members;

(6) Administrative Law Judges; and

(7) Administrative Appeals Judges.

B. The Appellate Division.

C. The Civil Remedies Division.

D. The Alternative Dispute Resolution Division.

E. The Medicare Operations Division.

C. Section AH.20 Functions. A. The Immediate Office of the Departmental Appeals Board assists the Chair in providing adjudicative and administrative services. The Chair is also a Board Member and provides leadership to the organizational components of the Board. The Chair is the appointed alternative dispute resolution specialist for the Department. The Deputy Chair acts for the Chair when absent and provides day to day management services. The Director of Administration assists the Chair in administrative matters and provides logistical support to the other organizational components of the Board. The Director of Mediation Services coordinates the Board's mediation and other alternative dispute resolution services. The Board Members hear and decide grant disputes and appeals, appeals from civil remedies cases, and other cases as assigned. The Administrative Law Judges hear and decide civil remedies cases, and other cases as assigned. The Administrative Appeals Judges hear and decide disputes relating to reimbursement for Medicare services, and other cases as assigned.

B. The Appellate Division provides attorney and other staff support to assist in the Board's administrative review of disallowances of federal grant funds under Title I, IV, X, XIV, XIX and XX of the Social Security Act; determinations by the Administrative Law Judges in civil remedies cases; disapprovals of state plans and state plan amendments under section 1116(a)(2) of the Social Security Act; disputes involving direct discretionary grants, cost allocation plans and indirect cost rates; disputes regarding allegations of scientific misconduct by the Office of Research Integrity, National Institutes of Health; disputes regarding quality control in the Aid to Families with Dependent Children program; and disputes involving civil rights reviews. The Division is headed by a supervisory attorney who manages the Division's resources and advises Board Members. Attorneys in the Division research legal issues, review and evaluate case files, briefs and transcripts; conduct pre-hearing proceedings; draft decisions; provide advice and assistance to Board Members on the conduct of cases and decisions; and participate in hearings.

C. The Civil Remedies Division provides attorney and other staff support to assist in the hearing and disposition of civil remedies cases. The civil remedies cases include (1) Sanctions by the Food and Drug Administration, the Health Care Financing Administration, and the Inspector General against persons and entities associated with participation as a provider in federally funded health care programs or as any employee, contractor, or other fiscal relationship with the Department; (2) contract declinations and other adverse actions by the Indian Health Service; and (3) termination of federal funding by the Office for Civil Rights. The Division is headed by a supervisory attorney who also assigns cases to the Administrative Law Judges. Attorneys and Paralegal Specialists in the Division research legal issues; review and evaluate case files, briefs and transcripts; assist in pre-hearing proceedings; draft decisions; provide advice and assistance to Administrative Law Judges on the conduct of cases and decisions; and assist at hearings.

D. The Alternative Dispute Resolution Division provides alternative dispute resolution (ADR) services, including: mediation, early neutral evaluation, arbitration, regulatory negotiation, and facilitation. The Division also provides assistance in ADR systems design and training in a variety of substantive areas, including: conflict management, negotiations, interest-based bargaining, mediation, arbitration, and regulatory negotiation. The Division is headed by a Director of Mediation Services who provides overall substantive and resource management. Professional staff consist of attorneys and dispute resolution specialists who conduct ADR interventions and training.

E. The Medicare Operations Division provides attorney, paralegal and other staff support to assist in review of administrative law judge decisions regarding entitlement to coverage, health maintenance organizations,

inactions and claims filed by health care providers or Medicare beneficiaries for medical-related items or services provided or received for which payment or reimbursement is sought under title XVIII of the Social Security Act. The Division is headed by a chief who assigns cases and oversees the Division's operations. Paralegal specialists and other professional staff research and review claims, draft decisions, and provide advice and assistance to the Administrative Appeals Judges.

V. Delegation of Authority.

All delegations and redelegations of authority to officers and employees of the components which are affected by this reorganization, and which were in effect immediately prior to this reorganization will be continued in effect in them or their successors, pending further delegation, provided they are consistent with this reorganization.

Dated: September 29, 1995.

Donald E. Shalala,

Secretary.

[FR Doc. 95–24834 Filed 10–5–95; 8:45 am]

BILLING CODE 4110–60–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. FR–3778–N–57]

Federal Property Suitable as Facilities to Assist the Homeless

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

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, room 7256, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–1226; TDD number for the hearing-and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 56 FR 23789 (May 24, 1991) and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Brian Rooney, Division of Health Facilities Planning, U.S. Public Health Service, HHS, room 17A–10, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 56 FR 23789 (May 24, 1991).

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the Federal Register, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: U.S. Navy: John J. Kane, Deputy Division Director, Dept. of Navy, Real Estate Operations, Naval Facilities Engineering Command, 200 Stovall Street, Alexandria, VA 22332–2300; (703) 325–0474; Dept. of Veterans Affairs: Steve Koenig, Management Analyst, Dept. of Veterans Affairs, room 414 Lafayette Bldg., 811 Vermont Ave. NW., Washington, DC 20420; (202) 565–5424; U.S. Air Force: Carol Xander, Air Force Real Estate Agency (Area/MI), Bolling AFB, 172 Luke Avenue, Suite 104, Building 5683, Washington, DC 20332–5113; (202) 767–4034; (These are not toll-free numbers).

Dated: September 29, 1995.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM, FEDERAL REGISTER REPORT FOR 10/06/95

Suitable/Available Properties

Buildings (by State)

Alabama

Bldg. 19, VA Medical Center
Tuskegee Co: Macon AL 36083–
Landholding Agency: VA
Property Number: 979220006
Status: Underutilized
Comment: Portion of a 5320 sq. ft. 4-story structure

California

Bldg. 20, VA Medical Center
Wilshire & Sawtelle Blvds.
Los Angeles Co: Los Angeles CA 90073–
Landholding Agency: VA
Property Number: 979210003

Status: Unutilized
Comment: 8758 gross sq. ft., one story wooden, requires complete restoration meeting standards of national preservation laws and guidelines

Bldg. 13, VA Medical Center
Wilshire & Sawtelle Blvds.
Los Angeles Co: Los Angeles CA 90073–
Landholding Agency: VA
Property Number: 979220001
Status: Underutilized
Comment: portion of 66,165 sq. ft. bldg., needs major rehab, no util., pres. of asbestos, in historic district, potential to be hazardous due to storage of radioactive material nearby

Bldg. 156, VAMC
Wilshire & Sawtelle Blvds.
Los Angeles Co: Los Angeles CA 90073–
Landholding Agency: VA
Property Number: 979230015
Status: Underutilized
Comment: portion of 39,454 sq. ft. bldg., presence of asbestos, needs rehab, seismic reinforcement deficiencies, in his. district, potentially hazardous due to nearby radioactive material

Indiana

Bldg. 140, VAMC
East 38th Street
Marion Co: Grant IN 46952–
Landholding Agency: VA
Property Number: 979230007
Status: Underutilized
Comment: 60 sq. ft., concrete block bldg., most recent use—trash house, access restrictions

Montana

Facility #1
Havre Training Site
Co: Hill MT 59501–
Landholding Agency: Air Force
Property Number: 189530047
Status: Excess
Comment: 6843 sq. ft., 1 story brick frame, good condition, most recent use—technical training site

Pennsylvania

Bldg. 25, VA Medical Center
Delafield Road
Pittsburgh Co: Allegheny PA 15215–
Landholding Agency: VA
Property Number: 979210001
Status: Unutilized
Comment: 133 sq. ft., one story brick guard house, needs rehab

Tennessee

Bldg. 16, VAMC Mountain Home
Johnson Co: Washington TN 37604–
Landholding Agency: VA
Property Number: 979220007
Status: Unutilized
Comment: 3215 sq. ft., 3-story wood frame residence, needs repair, subject to historic preservation requirements

Wisconsin

Bldg. 8, VA Medical Center
County Highway E
Tomah Co: Monroe WI 54660–
Landholding Agency: VA
Property Number: 979010056
Status: Underutilized
Comment: 2200 sq. ft., 2 story wood frame, possible asbestos, potential utilities, structural deficiencies, needs rehab

Land (by State)

Alabama

VA Medical Center
VAMC
Tuskegee Co: Macon AL 36083–
Landholding Agency: VA
Property Number: 979010053
Status: Underutilized
Comment: 40 acres, buffer to VA Medical Center, potential utilities, undeveloped

California

Land
4150 Clement Street
San Francisco Co: San Francisco CA 94121–
Landholding Agency: VA
Property Number : 979240001
Status: Underutilized
Comment: 4 acres; landslide area

Maryland

VA Medical Center
9500 North Point Road
Fort Howard Co: Baltimore MD 21052–
Landholding Agency: VA
Property Number: 979010020
Status: Underutilized
Comment: Approx. 10 acres, wetland and periodically floods, most recent use—dump site for leaves

Texas

Land
Olin E. Teague Veterans Center
1901 South 1st Street
Temple Co: Bell TX 76504–
Landholding Agency: VA
Property Number: 979010079
Status: Underutilized
Comment: 13 acres, portion formerly landfill, portion near flammable materials, railroad crosses property, potential utilities

VA Medical Center
4800 Memorial Drive
Waco Co: McLennan TX 76711–
Landholding Agency: VA
Property Number: 979010081
Status: Underutilized
Comment: 2.3 acres, negotiating lease w/ Owens-Illinois Glass Plant, most recent use—parking lot

Wisconsin

VA Medical Center
County Highway E
Tomah Co: Monroe WI 54660–
Landholding Agency: VA
Property Number: 979010054
Status: Underutilized
Comment: 12.4 acres, serves as buffer between center and private property, no utilities

Suitable/Unavailable Properties

Buildings (by State)

California

Bldg. 116
VA Medical Center
Wilshire and Sawtelle Blvds.
Los Angeles Co: Los Angeles CA 90073–
Landholding Agency: VA
Property Number: 979110009
Status: Underutilized
Comment: 60309 sq. ft., 3 story brick frame, seismic reinforcement defics., underutil. port of bldg. used intermitly., needs rehab, poss. asbestos in pipes/floor tiles, site access lim

Florida

Bldg. 36, VAMC
10,000 Bay Pines Blvd.
Bay Pines Co: Pinellas, FL 33504–
Landholding Agency: VA
Property Number: 979230009
Status: Underutilized
Comment: portion of 15,984 sq. ft., 1 story concrete frame bldg., needs rehab, presence of asbestos, listed on Natl Register of Historic Places, access restrictions

Bldg. 37, VAMC
10,000 Bay Pines Blvd.
Bay Pines Co: Pinellas, FL 33504–
Landholding Agency: VA
Property Number: 979230010
Status: Underutilized
Comment: Third floor of a concrete frame bldg. (13,900 sq. ft.), presence of asbestos, listed on Natl Register of Historic Places, access restrictions

Indiana

Bldg. 24, VAMC
East 38th Street
Marion Co: Grant, IN 46952–
Landholding Agency: VA
Property Number: 979230005
Status: Underutilized
Comment: portion of 4135 sq. ft. 2-story wood structure, needs major rehab, no sanitary or heating facilities, presence of asbestos, access restrictions

Bldg. 105, VAMC
East 38th Street
Marion Co: Grant, IN 46952–
Landholding Agency: VA
Property Number: 979230006
Status: Underutilized
Comment: 310 sq. ft., 1 story stone structure, needs major rehab, no sanitary or heating facilities, access restrictions

Minnesota

Bldg. 227
Va Medical Center
Fort Snelling
St. Paul Co: Hennepin, MN 55111–
Landholding Agency: VA
Property Number: 979010033
Status: Unutilized
Comment: 850 sq. ft., 2 story wood frame and brick residence, utilities disconnected

New York

Bldg. 144, VAECC
Linden Blvd. and 179th St.
St. Albans Co: Queens, NY 11425–
Landholding Agency: VA
Property Number: 979210004
Status: Unutilized
Comment: 5215 sq. ft., 2 story wood frame residence, needs rehab, potential utilities

Bldg. 143, VAECC
Linden Blvd. and 179th St.
St. Albans Co: Queens NY 11425–
Landholding Agency: VA
Property Number: 979210005
Status: Unutilized
Comment: 5215 sq. ft., 2 story wood frame residence, needs rehab, potential utilities

Bldg. 142/146, VAECC
Linden Blvd. and 179th St.
St. Albans Co: Queens NY 11425–
Landholding Agency: VA
Property Number: 979210006
Status: Unutilized
Comment: 5215 sq. ft., 2 story wood frame residence with 380 sq. ft. attached garage, needs rehab, potential utilities

Pennsylvania

Bldg. 2, VAMC
1700 South Lincoln Avenue
Lebanon Co: Lebanon PA 17042–
Landholding Agency: VA
Property Number: 979230011
Status: Unutilized
Comment: portion of 16,360 sq. ft. 3-story structure, most recent use—storage

Bldg. 3, VAMC
1700 South Lincoln Avenue
Lebanon Co: Lebanon PA 17042–
Landholding Agency: VA
Property Number: 979230012
Status: Unutilized
Comment: Portion of bldg. (3850 and 4360 sq. ft.), most recent use—storage

Bldg. 103, VAMC
1700 South Lincoln Avenue
Lebanon Co: Lebanon PA 17042–
Landholding Agency: VA
Property Number: 979230014
Status: Unutilized
Comment: portion of 1215 sq. ft. 2-story stone farm house, needs repair

Wyoming

Bldg. 13
Medical Center
NW of town at the end of Fort Road
Sheridan Co: Sheridan WY 82801–
Landholding Agency: VA
Property Number: 979110001
Status: Unutilized
Comment: 3613 sq. ft., 3 story wood frame masonry veneered, potential utilities, possible asbestos, needs rehab

Bldg. 79
Medical Center
NW of town at the end of Fort Road
Sheridan Co: Sheridan WY 82801–
Landholding Agency: VA
Property Number: 979110003
Status: Unutilized
Comment: 45 sq. ft., 1 story brick and tile frame, limited utilities, most recent use—reservoir house, use for storage purposes

Land (by State)

Florida

Compound, VAMC
10,000 Bay Pines Blvd.
Bay Pines Co: Pinellas FL 33504–
Landholding Agency: VA
Property Number: 979230017
Status: Underutilized
Comment: approx. 7 acres, storage compound, partially wooded

Illinois

VA Medical Center
3001 Green Bay Road
North Chicago Co: Lake IL 60064–
Landholding Agency: VA
Property Number: 979010082
Status: Unutilized
Comment: 2.5 acres, currently being used as a construction staging area for the next 6–8 years, potential utilities

Michigan

VA Medical center
5500 Armstrong Road
Battle Creek Co: Calhoun MI 49016–
Landholding Agency: VA
Property Number: 979010015
Status: Underutilized
Comment: 20 acres, used as exercise trails and storage areas, potential utilities

Minnesota

Bldg. 227–229 Land
VA Medical Center
Fort Snelling
St Paul Co: Hennepin MN 55111–
Landholding Agency: VA
Property Number: 979010006
Status: Underutilized
Comment: 2.0 acres, potential utilities, buildings occupied, residence/garage
VA Medical Center
Near 5629 Minnehaha Avenue
Minneapolis Co: Hennepin MN 55417–
Location: Land (Site of Building 15, 16, 21, 48, 64, T10)
Landholding Agency: VA
Property Number: 979010024
Status: Underutilized
Comment: 12.1 acres, most recent use—parking, potential utilities

Land—12 acres
VAMC
Near 5629 Minnehaha Avenue
Minneapolis Co: Hennepin MN 55417–
Landholding Agency: VA
Property Number: 979010031
Status: Unutilized
Comment: 12 acres, possible asbestos, leased to department of Natural Resources as a park walking trail

New York

VA Medical Center
Fort Hill Avenue
Canandaigua CO; Ontario NY 14424–
Landholding Agency: VA
Property Number: 979010017
Status: Underutilized
Comment: 27.5 acres, used for school ballfield and parking, existing utilities easements, portion leased

Pennsylvania

VA Medical Center
New Castle Road
Butler Co: Butler PA 16001–
Landholding Agency: VA
Property Number: 979010016
Status: Underutilized
Comment: Approx. 9.29 acres, used for patient recreation potential utilities

Land No. 645
VA Medical Center
Highland Drive
Pittsburgh Co: Allegheny PA 15206–
Location: Between Campania and Wiltsie Streets
Landholding Agency: VA
Property Number: 979010080
Status: Unutilized
Comment: 41.97 acres, heavily wooded, property includes dump area and numerous site storm drain outfalls

Land—34.16 acres
VA Medical Center
1400 Black Horse Hill Road
Coatesville Co: Chester PA 19320–
Landholding Agency: VA
Property Number: 979340001
Status: Underutilized
Comment: 34.16 acres, open field, most recent use—recreation/buffer

Suitable/To be Excessed

Buildings (by State)

New York

Bldg. 1
Hancock Field
Syracuse Co: Onandaga NY 13211–
Landholding Agency: Air Force
Property Number: 189530048
Status: Excess
Comment: 4955 sq. ft., 2 story concrete block, needs rehab, most recent use—administration

Bldg. 2
Hancock Field
Syracuse Co: Onandaga NY 13211–
Landholding Agency: Air Force
Property Number: 189530049
Status: Excess
Comment: 1476 sq. ft., 1 story concrete block, needs rehab, most recent use—repair shop

Bldg. 6
Hancock Field
Syracuse Co: Onandaga NY 13211–
Landholding Agency: Air Force
Property Number: 189530050
Status: Excess
Comment: 2466 sq. ft., 1 story concrete block, needs rehab, most recent use—repair shop

Bldg. 11
Hancock Field
Syracuse Co: Onandaga NY 13211–
Landholding Agency: Air Force
Property Number: 189530051
Status: Excess
Comment: 1750 sq. ft., 1 story wood frame, needs rehab, most recent use—storage

Bldg. 8
Hancock Field
Syracuse Co: Onandaga NY 13211–
Landholding Agency: Air Force
Property Number: 189530052
Status: Excess
Comment: 1812 sq. ft., 1 story concrete block, needs rehab, most recent use—repair shop communications

Bldg. 14
Hancock Field
Syracuse Co: Onandaga NY 13211–
Landholding Agency: Air Force
Property Number: 189530053
Status: Excess
Comment: 156 sq. ft., 1 story wood frame, most recent use—vehicle fuel statione

Bldg. 30
Hancock Field
Syracuse Co: Onandaga NY 13211–
Landholding Agency: Air Force
Property Number: 189530054
Status: Excess
Comment: 3659 sq. ft., 1 story, needs rehab, most recent use—assembly hall

Bldg. 31
Hancock Field
Syracuse Co: Onandaga NY 13211–

Landholding Agency: Air Force
Property Number: 189530055
Status: Excess
Comment: 8252 sq. ft., 1 story concrete block, most recent use—storage

Bldg. 32
Hancock Field
Syracuse Co: Onandaga NY 13211–
Landholding Agency: Air Force
Property Number: 189530056
Status: Excess
Comment: 1627 sq. ft., 1 story concrete block, most recent use—storage

Land (by State)

Minnesota

Land around Bldg. 240–249, 253
VA Medical Center
Fort Snelling
St. Paul Co: Hennepin MN 55111–
Landholding Agency: VA
Property Number: 979010007
Status: Unutilized
Comment: 3.76 acres, potential utilities

New York

14.90 Acres
Hancock Filed
Syracuse Co: Onandaga NY 13211–
Landholding Agency: Air Force
Property Number: 189530057
Status: Excess
Comment: Fenced in compound, most recent use—Air Natl. Guard Communication & Electronics Group

Unsuitable Properties

Buildings (by State)

California

Bldg. 30735
Naval Air Weapons Center
China Lake Co: Kern CA 93555–
Landholding Agency: Navy
Property Number: 779530029
Status: Excess
Reason: Secured Area, Extensive deterioration

Indiana

Bldg. 21, VA Medical Center
East 38th Street
Marion Co: Grant IN 46952–
Landholding Agency: VA
Property Number: 979230001
Status: Underutilized
Reason: Extensive deterioration

Bldg. 22, VA Medical Center
East 38th Street
Marion Co: Grant IN 46952–
Landholding Agency: VA
Property Number: 979230002
Status: Underutilized
Reason: Extensive deterioration

Bldg. 62, VA Medical Center
East 38th Street
Marion Co: Grant IN 46952–
Landholding Agency: VA
Property Number: 979230003
Status: Underutilized
Reason: Extensive deterioration

Mississippi

Bldg. 6, Boiler Plant
Biloxi VA Medical Center
Biloxi Co: Harrison MS 39531–
Landholding Agency: VA
Property Number: 979410001
Status: Unutilized
Reason: Floodway

Bldg. 67
Biloxi VA Medical Center
Biloxi Co: Harrison MS 39531–
Landholding Agency: VA
Property Number: 9792410008
Status: Unutilized
Reason: Extensive deterioration

Bldg. 68
Biloxi VA Medical Center
Biloxi Co: Harrison MS 39531–
Landholding Agency: VA
Property Number: 9792410009
Status: Unutilized
Reason: Extensive deterioration

North Carolina

Bldg. 9
VA Medical Center
1100 Tunnel Road
Asheville Co: Buncombe NC 28805–
Landholding Agency: VA
Property Number: 979010008
Status: Underutilized
Reason: Other
Comment: Friable asbestos

Tennessee

Bldg. 60, VAMC Mountain Home
Johnson Co: Washington TN 37604–
Landholding Agency: VA
Property Number: 979220005
Status: Unutilized
Reason: Extensive deterioration

Texas

Bldg. 24
Olin E. Teague Veterans Center
1901 South 1st Street
Temple Co: Bell TX 76504–
Landholding Agency: VA
Property Number: 979010050
Status: Unutilized
Reason: Other
Comment: Friable asbestos

Bldg. 25
Olin E. Teague Veterans Center
1901 South 1st Street
Temple Co: Bell TX 76504–
Landholding Agency: VA
Property Number: 979010051
Status: Unutilized
Reason: Other
Comment: Friable asbestos

Bldg. 26
Olin E. Teague Veterans Center
1901 South 1st Street
Temple Co: Bell TX 76504–
Landholding Agency: VA
Property Number: 979010052
Status: Unutilized
Reason: Other
Comment: Friable asbestos

Wyoming

Bldg. 95
Medical Center
N.W. of town at the end of the Fort Road
Sheridan Co: Sheridan WY 82801–
Landholding Agency: VA
Property Number: 979110004
Status: Unutilized
Reason: Other
Comment: Sewage digester for disposal plant

Bldg. 96
Medical Center
N.W. of town at the end of the Fort Road
Sheridan Co: Sheridan WY 82801–
Landholding Agency: VA
Property Number: 979110005
Status: Unutilized
Reason: Other
Comment: Pump house for sewage disposal plant

Structure 99
Medical Center
N.W. of town at the end of the Fort Road
Sheridan Co: Sheridan WY 82801–
Landholding Agency: VA
Property Number: 979110006
Status: Unutilized
Reason: Other
Comment: Mechanical screen for sewage disposal plant

Structure 100
Medical Center
N.W. of town at the end of the Fort Road
Sheridan Co: Sheridan WY 82801–
Landholding Agency: VA
Property Number: 979110007
Status: Unutilized
Reason: Other
Comment: Dosing tank for sewage disposal plant

Structure 101
Medical Center
N.W. of town at the end of the Fort Road
Sheridan Co: Sheridan WY 82801–
Landholding Agency: VA
Property Number: 979110008
Status: Unutilized
Reason: Other
Comment: Chlorination chamber for sewage disposal plant

Bldg. 97, Medical Center
Sheridan Co: Sheridan WY 82801–
Landholding Agency: VA
Property Number: 979110011
Status: Unutilized
Reason: Other
Comment: Sewage disposal plant

Structure 98, Medical Center
Sheridan Co: Sheridan WY 82801–
Landholding Agency: VA
Property Number: 979110012
Status: Unutilized
Reason: Other
Comment: Sludge bed/sewage disposal plant

Land (by State)

California

DVA Medical Center
4951 Arroyo Road
Livermore Co: Alameda CA 94550–
Landholding Agency: VA
Property Number: 979110023
Status: Unutilized
Reason: Other
Comment: 750,000 gallon water reservoir

Florida

Bldg. Wildlife Sanctuary, VAMC
10,000 Bay Pines Blvd.
Bay Pines Co: Pinellas FL 33504–
Landholding Agency: VA
Property Number: 979230004
Status: Underutilized
Reason: Other

Comment: Inaccessible

Minnesota

VAMC
VA Medical Center
4801 8th Street No.
St. Cloud Co: Sterns MN 56303–
Landholding Agency: VA
Property Number: 979010049
Status: Underutilized
Reason: Within 2000 ft. of flammable or explosive material

New York

Tract 1
VA Medical Center
Bath Co: Steuben NY 14810–
Location: Exit 38 off New York State Route 17.
Landholding Agency: VA
Property Number: 979010011
Status: Unutilized
Reason: Secured Area

Tract 2
VA Medical Center
Bath Co: Steuben NY 14810–
Location: Exit 38 off New York State Route 17.
Landholding Agency: VA
Property Number: 979010012
Status: Underutilized
Reason: Secured Area

Tract 3
VA Medical Center
Bath Co: Steuben NY 14810–
Location: Exit 38 off New York State Route 17.
Landholding Agency: VA
Property Number: 979010013
Status: Underutilized
Reason: Secured Area

Tract 4
VA Medical Center
Bath Co: Steuben NY 14810–
Location: Exit 38 off New York State Route 17.
Landholding Agency: VA
Property Number: 979010014
Status: Unutilized
Reason: Secured Area

[FR Doc. 95–24721 Filed 10–5–95; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of amendment to Approved Tribal-State Compact.

SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the Federal Register, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the First Amendment to the Quileute Tribe—State of Washington Class III Gaming Compact, which was executed on July 6, 1995.

DATES: This action is effective October 6, 1995.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, D.C. 20240, (202) 219–4068.

Dated: September 15, 1995.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 95–24894 Filed 10–5–95; 8:45 am]

BILLING CODE 4310–02–M

Bureau of Land Management

[OR–015–95–1610–00: G5–222]

Tucker Hill Perlite Mining Plan of Operations; Draft Environmental Impact Statement; Notice of Availability

AGENCY: Bureau of Land Management (BLM), DOI.

ACTION: Notice of Availability, Tucker Hill Perlite Mining Plan of Operations Draft Environmental Impact Statement (DEIS).

SUMMARY: In accordance with section 102(c) of the National Environmental Policy Act, the Lakeview District has prepared a DEIS analyzing the potential environmental impacts of a proposed perlite mining operation in Lake County, Oregon. The DEIS is expected to be available for review on or about October 6, 1995.

Atlas Perlite, Inc. proposes to develop a 15–20 acre perlite quarry and associated waste rock dump on Tucker Hill located approximately 35 northwest of the town of Lakeview, Oregon. The total area of disturbance is estimated to be about 37 acres. The ore would be hauled from Tucker Hill to Lakeview where it would be crushed and transported via truck or rail to markets mainly in the northwest.

DATES: This notice announces the beginning of the 60-day public review period. The review period will officially close 60 days from the date the U.S. Environmental Protection Agency publishes its notice of availability of the DEIS.

ADDRESSES: Comments on the DEIS should be sent to Edwin J. Singleton, Lakeview District Manager, BLM, P.O. Box 151, Lakeview, OR 97630.

FOR FURTHER INFORMATION CONTACT: To obtain additional information on the proposal or to get a copy of the DEIS contact Ted Davis or Paul Whitman at address above or by telephone at (503) 947–2177.

SUPPLEMENTARY INFORMATION: Those individuals, organizations, native American tribes, agencies, and other governments with a known interest in the proposal have been sent a copy of the DEIS. Reading copies of the document are available at the Lake, Klamath, and Harney County, Oregon, libraries and at the Public Room, Oregon State Office, 1515 SW 5th, Portland, OR 97201. At this time there is no public meeting/hearing planned. However, one could be scheduled if there is sufficient interest. Anyone desiring a public meeting/hearing must request one, in writing, to the address above and provide substanative reasons for holding such a meeting/hearing.

M. Joe Tague,

Acting District Manager.

[FR Doc. 95–24836 Filed 10–5–95; 8:45 am]

BILLING CODE 4310–33–P

[CO–050–1610–00]

Front Range Resource Advisory Council (Colorado) Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972 (FACA), 5 U.S.C. Appendix, notice is hereby given that the next meeting of the Front Resource Advisory Council (Colorado) will be held on Wednesday, October 18, 1995, in Canon City, Colorado. The meeting is scheduled to begin at 9:00 a.m. at BLM's Canon City District Office, 3170 East Main Street, Canon City, Colorado. The agenda for the meeting will focus on the development of standards for rangeland health and guidelines for livestock grazing.

All Resource Advisory Council meetings are open to the public. Interested persons may make oral statements to the Council at 10 a.m. October 18, or written statements may be submitted for the Council's consideration. The District Manager may limit the length of oral presentations depending on the number of people wishing to speak.

DATES: The meeting is scheduled for Wednesday, October 18, 1995 from 9 a.m. to 5 p.m.

ADDRESSES: For further information, contact Ken Smith, Bureau of Land Management (BLM), Canon City District Office, 3170 East Main Street, Canon

City, Colorado 81212; Telephone (719) 275–0631; TDD (719) 275–4346.

SUPPLEMENTARY INFORMATION: Summary minutes for the Council meeting will be maintained in the Canon City District Office and will be available for public inspection and reproduction during regular business hours within thirty (30) days following the meeting.

Stuart L. Freer,

Associate District Manager.

[FR Doc. 95–24958 Filed 10–5–95; 8:45 am]

BILLING CODE 4310–JB–M

Fish and Wildlife Service

Availability of an Environmental Assessment/Habitat Conservation Plans and Receipt of Applications for Incidental Take Permits for Construction of Single Family Residences in Travis County, Texas

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The following Applicants have applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(a) of the Endangered Species Act (Act). The requested permits would authorize the incidental take of the endangered golden-cheeked warbler (*Dendroica chrysoparia*). The proposed take would occur as a result of the construction of single family residences in Austin, Travis County, Texas.

The Service has prepared the Environmental Assessment/Habitat Conservation Plans (EA/HCPs) for the incidental take applications. A determination of jeopardy to the (EA/HCPs) for the incidental take applications. A determination of jeopardy to the species or a Finding of No Significant Impact (FONSI) will not be made before 30 days from the date of publication of this notice. This notice is provided pursuant to Section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on the application should be received on or before November 6, 1995.

ADDRESSES: Persons wishing to review the application or the EA/HCPs may obtain copies by contacting Joseph E. Johnston or Mary Orms, Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, Texas 78758 (512/490–0063). Documents will be available for public inspection by written request, by appointment only, during normal business hours (8:00 to 4:30) U.S. Fish and Wildlife Service, Austin, Texas. Written data or comments concerning the application(s) and EA/HCPs should be submitted to the Acting Field Supervisor, Ecological Field Office, Austin, Texas (see **ADDRESSES** above). Please refer to the assigned permit number when submitting comments.

FOR FURTHER INFORMATION CONTACT: Joseph E. Johnston or Mary Orms at the above Austin Ecological Service Field Office.

SUPPLEMENTARY INFORMATION: Section 9 of the Act prohibits the ''taking'' of endangered species such as the golden-cheeked warbler. However, the Service, under limited circumstances, may issue permits to take endangered wildlife species incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for endangered species are at 50 CFR 17.22.

Applicant: Janis Goynes plans to construct a single family residence on Lot 8 on Lakeview Drive, Commanche Pass Section One Subdivision, Austin, Travis County, Texas. This action will eliminate less than one-half acre of land and indirectly impact less than one-half additional acre of golden-cheeked warbler habitat per residence. Permit number PRT–806825 has been assigned to this applicant, and this permit is a period of 1 year.

Applicant: Lance Brubaker plans to construct a single family residence on Lots 56 and 57, Cardinal Hills Subdivision, Unit 13, 15205 Storm Drive, Austin, Travis County, Texas. This action will eliminate one-half acre of land and indirectly impact one additional acre of golden-cheeked warbler habitat per residence. Permit number PRT–806827 has been assigned to this applicant, and this permit is a period of 2 years.

Applicant: Louie Hausman plans to construct a single family residence on Lot 131, 15101 Flamingo Drive South, Cardinal Hills Subdivision, Unit 3, Travis County, Texas. This action will eliminate less than one-half acre of land and indirectly impact less than one-half additional acre of golden-cheeked warbler habitat per residence. Permit number PRT–806829 has been assigned to this applicant, and this permit is a period of 1 year.

The applicants propose to compensate for this incidental take of golden-cheeked warbler habitat by placing $1,500 for each lot into the City of Austin Balcones Canyonlands Conservation Fund to acquire/manage lands for the conservation of golden-cheeked warbler. Alternatives to this action were rejected because selling or not developing the subject property with federally listed species present was not economically feasible.

Nancy M. Kaufman,

Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 95–24832 Filed 10–5–95; 8:45 am]

BILLING CODE 4510–55–M

National Park Service

Grand Portage National Monument and Isle Royale National Park; Concession Permit

AGENCY: National Park Service, Interior.

ACTION: Public notice.

SUMMARY: Public notice is hereby given that the National Park Service proposes to award a concession permit authorizing continued operation of boat transportation service between Grand Portage National Monument and Isle Royale National Park for the public at Isle Royale National Park, Michigan, for a period of approximately five (5) years from date of execution through December 31, 2000.

EFFECTIVE DATE: December 5, 1995.

ADDRESSES: Interested parties should contact the Superintendent, Isle Royale National Park, 800 East Lakeshore Drive, Houghton, Michigan 49931, to obtain a copy of the prospectus describing the requirements of the proposed permit.

SUPPLEMENTARY INFORMATION: This permit renewal has been determined to be categorically excluded from the procedural provisions of the National Environmental Policy Act and no environmental document will be prepared. The existing concessioner has performed its obligations to the satisfaction of the Secretary under an existing permit which expired by limitation of time on December 31, 1994, and therefore pursuant to the provisions of Section 5 of the Act of October 9, 1965 (79 Stat. 969; 16 USC 20), is entitled to be given preference in the negotiation of a new proposed permit providing the existing concessioner submits a responsive offer (a timely offer which meets the terms and conditions of the Prospectus). This means that the permit will be awarded to the party submitting the best offer, provided that if the best offer was not submitted by the existing concessioner, then the existing concessioner will be afforded the opportunity to match the best offer, then the permit will be awarded to the existing concessioner.

If the existing concessioner does not submit a responsive offer, the right of preference in renewal shall be considered to have been waived, and the permit will then be awarded to the

party that has submitted the best responsive offer.

The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal, including that of the existing concessioner, must be received by the Superintendent not later than the sixtieth (60) day following publication of this notice to be considered and evaluated.

Dated: September 11, 1995.

William W. Schenk,

Field Director, Midwest Region.

[FR Doc. 95–24933 Filed 10–5–95; 8:45 am]

BILLING CODE 4310–70–M

Office of the Secretary

[K00160–95–35150]

National Indian Gaming Commission

ACTION: Notice of proposed appointment to the Commission.

SUMMARY: The Indian Gaming Regulatory Act (25 U.S.C. 2701 et seq.) provides for appointment by the Secretary of the Interior of two associate members of the National Indian Gaming Commission after public notice and an opportunity for comment. Notice is hereby given of the proposed appointment of Philip N. Hogen as an associate member of the Commission.

DATES: Comments must be received by November 6, 1995.

ADDRESSES: Comments should be addressed to: Debbie Brown, Director, Division of Personnel Services, Minerals Management Service, Department of the Interior, 1849 C Street, N.W., Mail Stop 5459, Washington, D.C. 20240–0001.

FOR FURTHER INFORMATION CONTACT: Sharon D. Eller or Debbie Brown (202) 208–6702.

SUPPLEMENTARY INFORMATION: Section 5(a) of the Indian Gaming Regulatory Act (25 U.S.C. 2704(a)) establishes a three-member National Indian Gaming Commission within the Department of the Interior. The Act provides that the Chairman of the Commission is to be appointed by the President with advice and consent of the Senate. The two associate members of the Commission are to be appointed by the Secretary of the Interior (24 U.S.C. 2704(b)(1)). The Act provides that the Secretary shall publish notice of nominations for the associate member positions in the Federal Register and provide an opportunity for public comment (24 U.S.C. 2704 (b)(2)(B)).

Notice is hereby given of the proposed appointment of Philip N. Hogen to be associate member of the Commission for a term of three years.

Mr. Hogen is a partner in the law firm of DeMersseman Jensen in Rapid City, South Dakota, which he joined in 1993, where his practice focuses on litigation, Federal and administrative matters, and Indian law. In April 1992, Mr. Hogen became the first Director of the Office of American Indian Trust within the United States Department of the Interior. Prior to joining the Department of the Interior, Mr. Hogen served from 1981 to 1992 as the United States Attorney for the District of South Dakota. Before his appointment as U.S. Attorney, Mr. Hogen served as the States Attorney for Jackson County in Kadoka, South Dakota. He also served on the Rosebud Sioux Tribal Court of Appeals. In 1973 and 1974, he served as Congressman Jim Abdnor's first Administrative Assistant. His professional activities have included serving as Chairman of the Indian Affairs Subcommittee of the Attorney General's Advisory Committee of U.S. Attorneys, and as President of the South Dakota States Attorneys Association and on the Board of Directors of the National District Attorneys Association. In 1988, Mr. Hogen received the Attorney General's Award for Dedication and Leadership in the prosecution of crimes within Indian country. Mr. Hogen graduated from Augustana College in 1967, and holds a Juris Doctor from the University of South Dakota School of Law (1970). He is an enrolled member of the Oglala Sioux Tribe of the Pine Ridge Reservation in South Dakota.

Persons wishing to comment on this proposed appointment may submit written comments to the address identified above. Comments must be received by the date indicated above, which is 30 days from the date of publication of this notice.

Dated: September 26, 1995.

Bruce Babbitt,

Secretary of the Interior.

[FR Doc. 95–24893 Filed 10–5–95; 8:45 am]

BILLING CODE 4310–10–P

National Park Service

Concession Permit Proposal

AGENCY: National Park Service, Interior.

ACTION: Public notice.

SUMMARY: Public notice is hereby given that the National Park Service proposes to award a concession permit authorizing continued sale of photographic film, photographic supplies and sanitary napkins at Jefferson National Expansion Memorial National Historic Site, St. Louis, Missouri, for a period of five (5) years from September 1, 1995, through August 31, 2000.

EFFECTIVE DATE: December 5, 1995.

ADDRESSES: Interested parties should contact the Superintendent, Jefferson National Expansion Memorial National Historic Site, 11 North Fourth Street, St. Louis, Missouri 63102–1882, to obtain a copy of the prospectus describing the requirements of the proposed permit.

SUPPLEMENTARY INFORMATION: This permit renewal has been determined to be categorically excluded from the procedural provisions of the National Environmental Policy Act and no environmental document will be prepared.

Notwithstanding the provisions of Section 5 of the Concessions Policy Act (79 Stat. 969; 16 USC 20), the concessioner hereby waives its right to a preference in the renewal of this concession permit.

The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal, including that of the existing concessioner, must be received by the Superintendent not later than the sixtieth (60) day following publication of this notice to be considered and evaluated.

Dated: August 23, 1995.

William W. Schenk,

Field Director, Midwest Region.

[FR Doc. 95–24872 Filed 10–5–95; 8:45 am]

BILLING CODE 4310–70–M

Fish and Wildlife Service

Availability of an Environmental Assessment/Habitat Conservation Plan and Receipt of Application for Incidental Take Permit for Construction of One Single Family Residence on Lot 26, Block B, Lake Georgetown Estates, Williamson County, Texas

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Angela and Paul Murski (Applicants) have applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(a) of the Endangered Species Act (Act). The Applicant has been assigned permit numbers PRT–806824. The requested permit, which is for a period of 1 year, would authorize the incidental take of the endangered golden-cheeked warbler (*Dendroica chrysoparia*). The proposed take would

occur as a result of the construction of one single family residence at Lot 26, Block B, Lake Georgetown Estates, Williamson County, Texas. The Service has prepared the Environmental Assessment/Habitat Conservation Plan (EA/HCP) for the incidental take applications. A determination of jeopardy to the species or a Finding of No Significant Impact (FONSI) will not be made before 30 days from the date of publication of this notice. This notice is provided pursuant to Section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on the application should be received on or before November 6, 1995.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, New Mexico 87103. Persons wishing to review the EA/HCP may obtain a copy by contacting Joseph E. Johnston or Mary Orms, Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, Texas 78758 (512/490–0063). Documents will be available for public inspection by written request, by appointment only, during normal business hours (8:00 to 4:30), U.S. Fish and Wildlife Service, Austin, Texas. Written data or comments concerning the application(s) and EA/HCPs should be submitted to the Acting Field Supervisor, Ecological Field Office, Austin, Texas (see **ADDRESSES** above). Please refer to permit number PRT–806824 when submitting comments.

FOR FURTHER INFORMATION CONTACT: Joseph E. Johnston or Mary Orms at the above Austin Ecological Service Field Office.

SUPPLEMENTARY INFORMATION: Section 9 of the Act prohibits the ''taking'' of endangered species such as the golden-cheeked warbler. However, the Service, under limited circumstances, may issue permits to take endangered wildlife species incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for endangered species are at 50 CFR 17.22.

Applicant: Angela and Paul Murski plan to construct a single family residence on Lot 26, Block B, Lake Georgetown Estates, Williamson County, Texas. This action will eliminate less than one-half acre of land and indirectly impact less than one-half additional acres of golden-cheeked warbler habitat per residence. The applicant proposes to compensate for this incidental take of golden-cheeked warbler habitat by placing $1,500 into the City of Austin Balcones Canyonlands Conservation Fund to acquire/manage lands for the conservation of the golden-cheeked warbler.

Alternatives to this action were rejected because selling or not developing the subject property with federally listed species present was not economically feasible.

Nancy M. Kaufman,

Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 95–24833 Filed 10–6–95; 8:45 am]

BILLING CODE 4510–55–M

Office of Surface Mining Reclamation and Enforcement

Notice of Public Meeting and Request for Public Comments

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

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM or we) of the U.S. Department of the Interior is developing its recommendations to the President for the FY 1997 budget. As part of OSM's effort to be customer-driven, we are providing the public (you) with a chance to give us your recommendations on how much money we should ask for and how we should set our priorities to serve your needs. You can send us written comments. We will also hold a public meeting to give you and OSM's Management Council a chance to talk about FY 1997 priorities and funding levels. You can also let us know your views on other issues, but we prefer the focus to be on your priorities for FY 1997. The public meeting will be interactive, and will include several pre-selected roundtables. OSM will not respond directly to written comments or to the points raised in the public meeting. All points will be considered in the Management Council's deliberations. This is an experimental effort. If it works, we will use it in the future.

DATES: *Written comments:* We will accept written comments on the priority of our business lines and the program activities for fiscal year 1997 until 4:00 p.m. local time on November 1, 1995.

Public meeting: We will hold a public meeting in an interactive forum on our business lines and program activities for fiscal year 1997 in Washington, D.C. on October 31, 1995, beginning at 9:00 a.m. If more time is needed we will continue the meeting on November 1, 1995.

ADDRESSES: *Written comments:* Mail or hand-deliver to Victor J. Christiansen at the address provided under **FOR FURTHER INFORMATION CONTACT**.

Public meeting: The public meeting will be held at the South Interior Building's Auditorium, 1951 Constitution Ave., N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Victor J. Christiansen. Mr. Christiansen can supply information on our FY 1995–1996 budget for those interested, and may be reached at: Office of Surface Mining Reclamation and Enforcement, Room 244, 1951 Constitution Avenue, N.W., Washington, D.C. 20240; Telephone: 202–7851; E-Mail address on the internet; vchristi@osmre.gov.

SUPPLEMENTARY INFORMATION: OSM has decided to request public comments and to hold a public meeting where we hope to gain your input into our recommendations to the President on OSM's FY 1997 budget. To better enable you to prepare comments, we have included our mission and vision statements and a list of our business functions below. We would like you to prioritize the business lines and program activities, keeping in mind the mission and vision of OSM.

Mission

Our mission is to carry out the requirements of the Surface Mining Control and Reclamation Act in cooperation with States and Tribes. Our primary objectives are to ensure that coal mines are operated in a manner that protects citizens and the environment during mining and assures that the land is restored to beneficial use following mining, and to mitigate the effects of past mining by aggressively pursuing reclamation of abandoned coal mines.

Vision

In regulating active coal mining, we will maintain compliance at high levels and ensure that all mines are properly operated and promptly reclaimed to the standards established under the Act. We will emphasize prevention and ensure that long-term environmental problems do not occur. We will ensure that the premining productivity of the land is restored.

In reclaiming abandoned mine lands, we will aggressively pursue reclamation with a primary emphasis on correcting the most serious problems related to public health, safety, and the general welfare. We will ensure maximum public benefit through the prompt and fair distribution of public funds.

In cooperating with State regulatory authorities, the primary enforcers of SMCRA, and with Tribes, we will promote a shared commitment to the goals of the Act. We will develop

comprehensive understandings about the fairness, effectiveness, and efficiency of SMCRA programs. We will provide constructive program reviews, oversight monitoring, and technical assistance that focus on results. We will act independently to protect the public interest in situations of imminent harm or when a State does not implement an approved regulatory program.

In dealing with those who are affected by mining and reclamation, we will ensure the protection of citizens from abusive mining practices, be responsive to their concerns, and allow them full access to information needed to evaluate the effect of mining on their health, safety, general welfare, and property.

In our relations with the coal industry, we will have clear, fair, and consistently applied policies and will respect the importance of coal production as a source of our Nation's energy supply.

In all communications, we will maintain open, courteous, constructive, and timely dialogue and will use information to understand and improve our programs and those of our State and Tribal partners.

In demonstrating leadership in mining and reclamation, we will promote the development of the highest quality technical information and research and will seek the transfer of technology to those who would benefit.

In meeting our responsibilities, we will be a diverse, competent, innovative, and highly-trained work force. We will serve with integrity, and demonstrate technical, legal, administrative, and professional excellence at all times. We will constantly strive to create a more responsive, efficient, and effective process for achieving SMCA's objectives.

Business Lines and Program Activities

Financial Management involves the functions of collecting managing and disbursing the funds received from coal operators. This business line includes the costs of collecting, managing, disbursing and investing abandoned mine land reclamation fees. It also includes the full range of the audit, billing, and collection process. This line also finances the costs of collecting civil penalties from operators who violate any mining permit condition or any Title V SMCRA provision, as well as other administrative collections. It provides funds for protecting the environment, property and public.

Revenue Management—This program activity involves the identification, notification and collection of civil penalties and associated interest and bond forfeiture collections.

Fee Compliance—This program activity's primary purpose is to identify, notify, audit and collect fees from operators for the AML Fund. It is the AML Fund that provides monies for the reclamation of abandoned mine lands.

Financial Management—This program activity includes the programmatic accounting functions, such as AML and excluding administrative functions such as payroll. This also includes the fiscal responsibility and accounting for grants.

Environmental Restoration involves all those functions that contribute to reclaiming lands affected by past coal mining practices. This business line provides for the use of AML funds to protect public health, safety, and general welfare from extreme danger and adverse effects of coal mining practices. It also restores land and water resources and the environment previously degraded by these practices. In addition, OSM will finance the Appalachian Clean Streams Initiative in this business line.

The preponderance of the funding requirement is devoted to AML State reclamation funding. Also included in the grants area is funding for State operated emergency projects and priority projects. This business line also finances the costs of the Federal reclamation program, including the Federal emergency program and for priority projects in States that do not have a reclamation program. This business line also funds the costs of AML program development by providing resources for policy direction and program oversight.

State Funding—This program activity involves the funds allocated to the States for their approved AML programs. This does not include grant application processing or any other processes for administering the grants.

State Performance Evaluation—This program activity provides for monitoring the progress and quality of each approved State and Tribal reclamation plan.

Emergencies—This program activity provides for immediate relief from abandoned mine hazards that threaten public safety and health. It provides for implementation of the emergency program in States and Tribal lands without approved emergency reclamation programs.

Federal/Indian Lands—This program activity provides for the management of AML projects in States and Tribal lands without approved reclamation plans under the Federal Reclamation Program.

Program Development and Maintenance—The Program Development activity provides for developing an allocation and distribution formula for grants to the States and Indian Tribes; management and maintenance of the National Abandoned Mine Land Inventory; development and implementation of the Appalachian Clean Streams Initiative; and the application and development of policies and regulations related to Title IV of SMCRA.

Environmental Protection ecnompasses those functions that directly contribute to ensuring that the environment is protected during surface coal mining operations. It also assures that coal operators adequately reclaim the land after the mining is complete.

This business line involved the oversight of State programs and the operation of Federal and Indian programs. As with the Environmental Restoration business line, the principal costs of delivering the Environmental Protection line are devoted to providing regulatory grants to the States. Other important responsibilities financed out of this business line include State program oversight through the inspection and evaluation processes and the operation of the Applicant Violator System. OSM funds State regulatory program development in this business line.

This business line also provides OSM with the resources needed to oversee Federal and Indian programs. It includes direct inspection and enforcement activities on Indian lands and in States not having primacy, and in States who have not entered into cooperative agreements to oversee Federal lands within their borders. It also provides for OSM's costs for regulatory program development.

State Funding—This program activity involves the grant funds OSM must allocate to each State with an approved regulatory program to fund up to 50% of their programs. This program does not include processing grant applications or any other processes necessary to disburse the grants to the states.

State Performance Evaluation—Includes those program activities associated with the assurance that the states are following the approved regulatory and abandoned mine land programs.

Federal Programs—Includes those program activities associated with establishing/maintaining a Federal presence to carry out the requirements of SMCRA.

Federal Lands—Includes those program activities associated with the negotiation and monitoring of cooperative agreements with primacy states to regulate coal mining on Federal

lands in their states; also includes direct regulatory activities on Federal lands in states without cooperative agreements.

Indian Lands—Includes direct regulatory activities on Indian lands and initiatives in self-governance and self-determination.

Program Development and Maintenance—Includes those program activities associated with the interpretation of SMCRA and its implementing regulations, reviewing and processing amendments to state programs and developing new program initiatives to meet changes in regulatory policy.

Applicant Violator System (AVS)—This program activity provides OSM, the states and tribes with the required information to fully meet the requirements of Section 510(c) of the Surface Mining Act.

Technology Development and Transfer captures OSM efforts to enhance the technical skills that States and Indian tribes need to operate their regulatory and reclamation programs and to meet SMCRA requirements. OSM wants to assure that States and Indian tribes have the highest possible level of technical capabilities necessary to run effective programs.

OSM provides technical outreach to States and Indian tribes in a multi-disciplinary approach to solve problems related to the environmental effects of coal mining. OSM provides daily informal assistance to States and Indian tribes. It also conducts technical studies on mining related problems and shares the results with them.

This business line provides the resources necessary to operate the Technical Information Processing system. This business line also funds OSM's technical training program by providing an ongoing formal educational program to increase the technical competence of OSM, State and Tribal personnel. It also funds COALEX, a computer assisted library search service, used to aid regulatory authorities by providing legal information on SMCRA, its implementing regulations and State regulatory information.

Training—The training program activity provides technical assistance to State, Tribal and OSM personnel by developing, conducting, evaluating, and/or coordinating all OSM training activities.

Technical Assistance—The technical assistance program activity addresses technical problems which arise during implementing of SMCRA. This includes assistance and advice to State, Tribal, and OSM personnel on specific issues related to Titles IV and V of SMCRA, and current and effective methodology on mining and reclamation. This program area also includes the operation and maintenance of the Technical Information Processing System (TIPS), technical input for State program evaluation, assistance/testimony in court cases/hearings, preparation of technical studies, and interaction/coordination with other agencies on technical issues.

Technology Transfer—The technology transfer program activity provides assistance to customers in the understanding of SMCRA and in the dissemination of technical methods of achieve the requirements of SMCRA. This includes participation in technical meetings, interactive forums, and workshops; providing displays and speakers for conferences/seminars; and providing access and maintenance to information systems such as COALEX/LEXIS.

To assist us prioritize these business lines and program activities we have scheduled a public meeting on the fiscal year 1997 budget in Washington, D.C. Refer to **DATES** and **ADDRESSES** for the time, date and location for the meeting. The meeting will continue until everyone has had an opportunity to be heard. We will not prepare a formal transcript of the meeting, nor do we plan to provide formal responses to the written comments. We hope that this will facilitate dialogue in the interactive forum.

Any disabled individual who needs special accommodation to attend the public meeting should contact the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: September 29, 1995.

Robert Uram,

Director, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 95–24897 Filed 10–5–95; 8:45 am]

BILLING CODE 4310–05–M

INTERSTATE COMMERCE COMMISSION

Notice of 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).

1. parent corporation and address of principal office:

Explosives Technologies International, Inc. (ETI), Wilson Bldg., Suite 202, 3511 Silverside Road, Wilmington, DE 19810–4902

2. Wholly-owned Subsidiaries which will participate in the operations, and State(s) of incorporation:

(i) Blastrite Services Inc., Incorporated—South Carolina; Incorporated—Georgia; Incorporated—Virginia

(ii) Rimrock Explosives Inc., Incorporated—Idaho

(iii) Southern Explosives Corporation, Incorporated—Kentucky

(iv) United Explosives Company of Ohio, Incorporated—Ohio

(v) Explosives Energies Inc., Incorporated—Missouri

(vi) Golden State Explosives Inc., Incorporated—California

(vii) Explosives Energies Inc., dba Arkansas Explosives, Incorporated—Arkansas

(viii) Explo-Tech Inc., Incorporated—Pennsylvania; Incorporated—Maryland

(ix) North Star Explosives Inc., Incorporated—Alaska

(x) ACE Explosives ETI Ltd., Incorporated—Canada

(xi) Explosifs ETI (Quebec) Inc., Incorporated—Canada

Vernon A. Williams,

Secretary.

[FR Doc. 95–24907 Filed 10–5–95; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–447X]

Muncie and Western Railroad Company—Abandonment Exemption—in Delaware County, IN

AGENCY: Interstate Commerce Commission.

ACTION: Notice of Exemption.

SUMMARY: The Commission, under 49 U.S.C. 10505, exempts from the prior approval requirements of 49 U.S.C. 10903–04 Muncie and Western Railroad Company's ''whole-line abandonment'' of its 3.72-mile line of railroad within the Macedonia industrial commercial site in Muncie, Delaware County, IN.

DATES: Provided no formal expression of intent to file an offer of financial assistance has been received, this exemption will be effective on November 5, 1995. Formal expressions of intent to file an offer [1] of financial assistance under 49 CFR 1152.27(c)(2) must be filed by October 16, 1995; petitions to stay must be filed by October 23, 1995; requests for a public use condition must be filed by October

[1] *See Exempt. of Rail Abandonment—Offer of Finan. Assist.*, 4 I.C.C.2d 164 (1987).

26, 1995; and petitions to reopen must be filed by October 31, 1995.

ADDRESSES: Send pleadings referring to Docket No. AB–447X to: (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, 1201 Constitution Avenue, N.W., Washington, DC 20423; and (2) Petitioner's representative: Thomas F. McFarland, Jr., Belnap, Spencer, McFarland & Herman, 20 North Wacker Drive, Suite 3118, Chicago, IL 60606–3101.

FOR FURTHER INFORMATION CONTACT: Beryl Gordon, (202) 927–5610. [TDD for the hearing impaired: (202) 927–5721.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: DC NEWS & DATA, INC., Interstate Commerce Commission Building, 1201 Constitution Avenue, N.W., Room 2229, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services at (202) 927–5721.]

Decided: September 27, 1995.

By the Commission, Chairman Morgan, Vice Chairman Owen, and Commissioners Simmons and McDonald.

Vernon A. Williams,

Secretary.

[FR Doc. 95–24906 Filed 10–5–95; 8:45 am]

BILLING CODE 7035–01–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) No.1063]

RIN 1121–ZA25

National Institute of Justice ''Solicitation for the Forensic DNA Laboratory Program''

AGENCY: U.S. Department of Justice, Office of Justice Programs, National Institute of Justice.

ACTION: Announcement of the availability of the National Institute of Justice's ''Solicitation for the Forensic DNA Laboratory Program.''

ADDRESSES: National Institute of Justice, 633 Indiana Avenue, NW., Washington, D.C. 20531.

DATES: The deadline for receipt of proposals is close of business on November 30, 1995.

FOR FURTHER INFORMATION CONTACT: Dr. Richard M. Rau, National Institute of Justice, at (202) 307–0648.

SUPPLEMENTARY INFORMATION: The following supplementary information is provided:

Authority

This action is authorized under the Omnibus Crime Control and Safe Streets Act of 1968, §§ 201–03, as amended, 42 U.S.C. 3721–23 (1988).

Background

The purpose of this solicitation is to provide funding to State and local governments to develop or improve the capability to analyze deoxyribonucleic acid (DNA) in State and local forensic laboratories. This program is authorized by the DNA Identification Act of 1994 (Public Law 103–322). Interested persons should call the National Criminal Justice Reference Service (NCJRS) at 1–800–851–3420 to obtain a copy of ''Solicitation for the Forensic DNA Laboratory Program'' (refer to document no. SL000135). The solicitation is available electronically via the NCJRS Bulletin Board, which can be accessed via Internet. Telnet to ncjrsbbs.aspensys.com, or gopher to ncjrs.aspensys.com 71. Those without Internet access can dial the NCJRS Bulletin Board via modem: dial 301–738–8895. Set modem at 9600 baud, 8–N–1.

Jeremy Travis,

Director, National Institute of Justice.

[FR Doc. 95–24874 Filed 10–5–95; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

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, 40 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 wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on 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–3104, Washington, D.C. 20210.

New General Wage Determination Decisions

The number of the decisions added to the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts'' are listed by Volume and State:

Volume II

District of Columbia
DC950003 (Oct. 6, 1995)

Modifications to General Wage Determination Decisions

The number of 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 and State. Dates of publication in the Federal Register are in parentheses following the decisions being modified.

Volume I

Massachusetts
MA950001 (Feb. 10, 1995)
MA950002 (Feb. 10, 1995)
MA950003 (Feb. 10, 1995)
MA950005 (Feb. 10, 1995)
MA950007 (Feb. 10, 1995)
MA950012 (Feb. 10, 1995)
MA950013 (Feb. 10, 1995)
MA950014 (Feb. 10, 1995)
MA950015 (Feb. 10, 1995)
MA950017 (Feb. 10, 1995)
MA950018 (Feb. 10, 1995)
MA950019 (Feb. 10, 1995)
MA950021 (Feb. 10, 1995)
New Jersey
NJ950002 (Feb. 10, 1995)
NJ950003 (Feb. 10, 1995)
NJ950007 (Feb. 10, 1995)
New York
NY950002 (Feb. 10, 1995)
NY950007 (Feb. 10, 1995)
NY950008 (Feb. 10, 1995)
NY950021 (Feb. 10, 1995)
NY950022 (Feb. 10, 1995)
NY950048 (Feb. 10, 1995)
NY950050 (Feb. 10, 1995)
NY950051 (Feb. 10, 1995)
NY950060 (Feb. 10, 1995)
NY950072 (Feb. 10, 1995)

Volume II:

District of Columbia

DC950001 (Feb. 10, 1995)
Pennsylvania
PA950001 (Feb. 10, 1995)
PA950002 (Feb. 10, 1995)
PA950003 (Feb. 10, 1995)
PA950004 (Feb. 10, 1995)
PA950005 (Feb. 10, 1995)
PA950006 (Feb. 10, 1995)
PA950008 (Feb. 10, 1995)
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PA950042 (Feb. 10, 1995)
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PA950052 (Feb. 10, 1995)
PA950054 (Feb. 10, 1995)
PA950060 (Feb. 10, 1995)
PA950063 (Feb. 10, 1995)
PA950065 (Feb. 10, 1995)
Virginia
VA950025 (Feb. 10, 1995)
VA950059 (Feb. 10, 1995)

Volume III:

Alabama
AL950003 (Feb. 10, 1995)
AL950004 (Feb. 10, 1995)
AL950006 (Feb. 10, 1995)
AL950008 (Feb. 10, 1995)
AL950017 (Feb. 10, 1995)
AL950034 (Feb. 10, 1995)
AL950042 (Feb. 10, 1995)
AL950044 (Feb. 10, 1995)
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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.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at (703) 487–4630.

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Signed at Washington, DC this 29th day of September 1995.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 95–24711 Filed 10–5–95; 8:45 am]

BILLING CODE 4510–27–M

Bureau of International Labor Affairs

U.S. National Administrative Office; National Advisory Committee for the North American Agreement on Labor Cooperation; Notice of Meeting

AGENCY: Office of the Secretary, Labor.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act (Pub. L. 92–463), the U.S. National Administrative Office (NAO) gives notice of the first meeting of the National Advisory Committee for the North American Agreement on Labor Cooperation (NAALC), which was established by the Secretary of Labor.

The Committee was established to provide advice to the U.S. Department of Labor on matters pertaining to the implementation and further elaboration of the labor side accord to the North American Free Trade Agreement (NAFTA). The Committee is authorized under Article 17 of the NAALC.

The Committee consists of a group of 12 independent representatives drawn from among labor organizations, business and industry, and educational institutions.

DATES: The Committee will meet on November 7, 1995 from 9:00 a.m. to 2:00 p.m.

ADDRESSES: U.S. Department of Labor, 200 Constitution Avenue, N.W., Room S–1011, Washington, D.C. 20210. The meeting is open to the public on a first-come, first-served basis.

FOR FURTHER INFORMATION CONTACT: Irasema Garza, Designated Federal Officer, U.S. NAO, U.S. Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Room C–4327, Washington, D.C. 20210. Telephone: 202–501–6653 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Please refer to the notices published in the Federal Register on December 15, 1994 (59 FR 64713) and August 11, 1995 (60 FR 41118) for supplementary information.

Signed at Washington, D.C. on October 1, 1995.

Irasema T. Garza,

Secretary, U.S. National Administrative Office.

[FR Doc. 95–24856 Filed 10–5–95; 8:45 am]

BILLING CODE 4510–28–M

Occupational Safety and Health Administration

[Docket No. NRTL–2–94]

Electro-Test, Inc.

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Notice of recognition as a nationally recognized testing laboratory.

SUMMARY: this notice announces the Agency's final decision on the application of Electro-Test, Inc. for recognition as a Nationally Recognized Testing Laboratory (NRTL) under 29 CFR 1910.7.

EFFECTIVE DATE: This recognition will become effective on October 6, 1995 and will be valid for a period of five years from that date, until October 6, 2000.

FOR FURTHER INFORMATION CONTACT: Office of Variance Determination, NRTL Recognition Program, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N3653, Washington, D.C. 20210.

SUPPLEMENTARY INFORMATION:

Notice of Final Decision

Notice is hereby given that Electro-Test, Inc. (ETI) which made application pursuant to section 6(b) of the Occupational Safety and Health Act of 1970, (84 Stat. 1593, 29 U.S.C. 655), Secretary of Labor's Order No. 1–90 (55 FR 9033), and 29 CFR 1910.7, for recognition as a Nationally Recognized Testing Laboratory, has been recognized as an NRTL for the equipment or material listed below.

The addresses of the laboratories covered by this application are:

Electro-Test, Inc., 5645 Gibraltar Drive, Pleasanton, California 94588

Electro-Test, Inc., 5370 E. Hunter Avenue, Anaheim, California 92807

Background

Electro-Test, Inc. is a privately held organization incorporated in the State of California in 1971. It has two facilities in California, one in Pleasanton which it has owned since 1992, and the other smaller facility in Anaheim. Most of the testing at Anaheim is performed at the site of the installation by ETI test engineers.

On June 9, 1995, the Occupational Safety and Health Administration published a notice of application for recognition as a nationally recognized testing laboratory of Electro-Test, Inc. in the Federal Register (60 FR 30595), pursuant to 29 CFR 1910.7. The notice included a preliminary finding that Electro-Test, Inc. could meet the requirements for recognition detailed in 29 CFR 1910.7 and it invited public comment on the application by August 8, 1995.

On July 18, 1995, the Building Codes Division, Department of Consumer and Business Services of the State of Oregon submitted comments favoring ETI's recognition as an NRTL based upon their past experiences with the applicant. This was the only comment received in response to the Federal Register notice.

Capability

Section 1910.7(b)(1) states that for each specified item of equipment or material to be listed, labeled or accepted, the laboratory must have the

capability (including proper testing equipment and facilities, trained staff, written testing procedures, and calibration and quality control programs) to perform appropriate testing.

The on-site review report indicates that ETI has facilities, personnel, and testing equipment which are appropriate for the area of recognition it seeks. The ETI Pleasanton, CA corporate headquarters' policies and procedures, operations manual, quality control manual, as well as the procedure manual for the ANSI/UL test standard are in effect at the Anaheim, CA facility. The laboratories have available all of the general test equipment necessary to perform the testing necessary for the area of recognition it seeks, with the possible exception of very specialized tests which may require equipment or facility leasing. Where it becomes necessary in the future, test equipment will be purchased or constructed.

The two ETI facilities have adequate equipment calibration procedures. The calibration laboratory manager at the Pleasanton facility is responsible for the calibration program. At the Anaheim facility a calibration specialist, who reports to the calibration laboratory manager in Pleasanton, is responsible for the calibration program. Calibration intervals are generally on a six-month basis and are typically shorter, never longer, than manufacturers' recommendations.

The general application and labeling processes are described in the ETI Operations Manual. This manual, together with the data sheets and national test standards, collectively specify the records that are to be maintained for an investigation. ETI has additional procedures that are applicable for specialized tests. The Manual also provides letter and report formats as well as the appeals procedure.

While ETI has a Quality Control and Audit Manual, quality aspects are also included in the Safety Manual, Compliance Labeling and Field Evaluation Manual (part of the ETI Operations Manual), Calibration Laboratory Quality Assurance and Operations Procedure Manual, and the General Policy Manual. The department/division managers are responsible for maintaining quality assurance, while the Vice President of Operations has the responsibility to verify compliance with procedures.

ETI has developed a Quality Audit Plan for internal auditing. The Quality Assurance program includes a description of the quality system, frequency of audits, responsibilities, method of reporting audit results, documenting deficiencies, a method of tracking corrective action, and audit content using an audit checklist for complete coverage.

Follow-Up and Field Inspection Procedures

Section 1910.7(b)(2) requires that the NRTL provide certain follow-up procedures, to the extent necessary, for the particular equipment or material to be listed, labeled, or accepted. These include implementation of control procedures for identifying the listed or labeled equipment or materials, inspecting the production run at factories to assure conformance with test standards, and conducting field inspections to monitor and assure the proper use of the label.

ETI has a written Follow-Up Inspection program which includes a written agreement, manufacturer participation requirements, certification, record keeping, continued conformance, and site inspection intervals and review procedures. In addition, before use of the ETI certification mark is permitted, ETI will inspect the manufacturer's record system, quality system, and production testing.

Independence

Section 1910.7(b)(3) requires that the NRTL be completely independent of employers subject to the tested equipment requirements, and for any manufacturers or vendors of equipment or materials being tested for these purposes.

OSHA believes, based upon an examination of the application, that Electro-Test, Inc. is independent of employers subject to the tested equipment requirements and of any manufacturers or vendors of equipment or materials being tested for these purposes, within the meaning of 29 CFR 1910.7(b)(3).

Creditable Reports/Complaint Handling

Section 1910.7(b)(4) provides that an OSHA recognized NRTL must maintain effective procedures for producing creditable findings and reports that are objective and without bias, as well as for handling complaints and disputes under a fair and reasonable system.

ETI's application as well as the on-site review report indicate that ETI does maintain effective procedures for producing creditable findings and reports that are objective.

The various manuals describe in detail the procedures for testing and for all written reports, as well as record keeping requirements, including retention times.

With regard to the handling of complaints or contested results, if clients, ETI personnel, users, or others file a complaint or disagree with a decision relating to the test standard, engineering, use, or inspection, they can present and discuss their views with various administrative levels of ETI personnel, up to and including the Chief Operating Officer in an attempt to resolve any disagreement.

Test Standards

Section 1910.7 requires that an NRTL use ''appropriate test standards'', which are defined, in part, to include any standard that is currently designated or an American Society for Testing and Materials (ASTM) test standard used for evaluation of products or materials. The standard for which ETI applied is an American National Standards Institute (ANSI) safety designated product standard.

Programs and Procedures

ETI administers two operational programs and procedures which have been examined and found to be acceptable to OSHA on the basis of the procedures and specific criteria as detailed in 60 FR 12980, March 9, 1995, pertaining to the types and programs and procedures that NRTLs may engage in under the OSHA/NRTL program.

Basic Program—This program is one in which ETI performs all of the necessary product testing and evaluation in-house prior to issuing a certification.

Witnessed Test Data Program—This program is utilized when characteristics such as the size, complexity, or uniqueness of a product require testing at the manufacturer's facility. The tests are in accordance with the appropriate recognized standard and are witnessed by an ETI compliance engineer. Specific minimum conditions will be followed to assure equivalency with tests conducted by ETI personnel, and the results will be recorded.

Final Decision and Order

Based upon a preponderance of the evidence resulting from an examination of the complete application, the supporting documentation, and the OSHA staff finding including the on-site report, OSHA finds that Electro-Test, Inc. has met the requirements of 29 CFR 1910.7 to be recognized by OSHA as a Nationally Recognized Testing Laboratory to test and certify certain equipment or materials.

Pursuant to the authority in 29 CFR 1910.7, Electro-Test, Inc. is recognized as a Nationally Recognized Testing

Laboratory subject to the limitations and conditions listed below:

Limitations

This recognition is limited to equipment or materials which, under 29 CFR Part 1910, require testing, listing, labeling, approval, acceptance, or certification, by a Nationally Recognized Testing Laboratory. This recognition is limited to the use of the following test standard for the testing and certification of equipment or materials included within the scope of this standard:

- ETI has stated that the standard is utilized to test equipment or materials which may be used in environments under OSHA's jurisdiction. This standard is considered appropriate under 29 CFR 1910.07(c): ANSI/UL 508—Industrial Control Equipment.

Conditions

Electro-Test, Inc. shall also abide by the following conditions of its recognition, in addition to those already required by 29 CFR 1910.7:

- The Occupational Safety and Health Administration shall be allowed access to ETI's facilities and records for purposes of ascertaining continuing compliance with the terms of its recognition and to investigate as OSHA deems necessary;
- If ETI has reason to doubt the efficacy of any test standard it is using under this program, it shall promptly inform the organization that developed the test standard of this fact and provide that organization with appropriate relevant information upon which its concerns are based;
- ETI shall not engage in or permit others to engage in any misrepresentation of the scope or conditions of its recognition. As part of this condition, ETI agrees that it will allow no representation that it is either a recognized or accredited Nationally Recognized Testing Laboratory (NRTL) without clearly indicating the specific equipment or material to which this recognition is tied, or that its recognition is limited to certain products;
- ETI shall inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, including details;
- ETI shall continue to meet the requirements for recognition in all areas where it has been recognized; and
- ETI shall always cooperate with OSHA to assure compliance with the spirit as well as the letter of its recognition and 29 CFR 1910.7.

Effective Date: This recognition will become effective on October 6, 1995 and will be valid for a period of five years from that date, until October 6, 2000, unless terminated prior to that date, in accordance with 29 CFR 1910.7.

Signed at Washington, D.C. this 2nd day of October 1995.

Joseph A. Dear,

Assistant Secretary.

[FR Doc. 95–24941 Filed 10–5–95; 8:45 am]

BILLING CODE 4510–26–M

Pension and Welfare Benefits Administration

[Application No. D–10096, et al.]

Proposed Exemptions; Profit Sharing Plan of NEBCO, Inc.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of proposed exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restriction of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

WRITTEN COMMENTS AND HEARING REQUESTS: All interested persons are invited to submit written comments or request for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this Federal Register Notice. Comments and request for a hearing should state: (1) the name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, Room N–5649, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Attention: Application No. stated in each Notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–5507, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

NOTICE TO INTERESTED PERSONS: Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the Federal Register. Such notice shall include a copy of the notice of proposed exemption as published in the Federal Register and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Profit Sharing Plan of NEBCO, Inc. (the Plan) Located in Lincoln, Nebraska

[Application No. D–10096]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted the restrictions of sections 406(a) and 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to (1) the proposed extensions of credit in the form of guarantees and advances of funds (the Advances) to the Plan by NEBCO, Inc. (the Employer), the sponsor of the Plan, with respect to the Guaranteed Investment Contract No. 64238 (the GIC) issued by Confederation Life Insurance Company of Canada (Confederation);

and (2) the repayment of the Advances by the Plan to the Employer; provided that the following conditions are satisfied: (a) All terms and conditions of the transactions are no less favorable to the Plan than those which the Plan would receive in arm's-length transactions; (b) No interest payments or expenses will be incurred by the Plan with respect to the transactions; (c) Repayment of the Advances will be restricted to proceeds from the GIC (GIC Proceeds); (d) Repayment of Advances will be waived by the Employer to the extent that Advances exceed the GIC Proceeds; and (e) All unpaid principal and earned interest of the GIC will be completely paid by the Advances to the Plan by March 15, 2000.

Summary of Facts and Representations

1. The Employer, which has been in business since 1910, is a privately-owned Nebraska corporation. It is primarily engaged in the production, manufacture, and sale and resale of construction materials. These materials include, among other things, sand and gravel, pipe, ready mixed concrete block, and other prestressed products. Its principal place of business is Lincoln, Nebraska and it employs approximately 500 individuals.

2. The Plan is a defined contribution profit sharing plan, providing for individually-directed participant accounts, which includes a cash or deferred arrangement that is intended to qualify under sections 401(a) and 401(k) of the Code. As of December 31, 1994, the Plan had 414 participants and total assets of $18,947,900.00.

The Employer is the administer and named fiduciary as prescribed by the Act. Authority to administer and manage the Plan has been allocated by the Employer to the Retirement Committee (the Committee), which is appointed annually from the officers of the Employer by its Board of Directors.[1]

With the respect to the Plan, the duties of the Committee include, *inter alia,* selecting trustees, portfolio managers, and the investment options for the participants, as well as monitoring the investment performance of the assets of the Plan. In performing its duties, the Committee has selected four different funds for the participants to direct the investment of assets in their respective Plan accounts, which include the following: (a) The Bond Fund, (b) the Equity Fund, (c) the International Equity Fund, and (d) the Stable Value Fund.

The Bond Fund is managed by FirsTier Financial, Inc., a regional multi-bank holding company incorporated and headquartered in Nebraska.

The assets of the Equity Fund offers three different investment options: the Washington Mutual Investors Fund; the American Mutual Funds; and E.B. Growth Stock Fund. The first two options are registered mutual funds and the third is a bank collective trust fund managed by FirsTier Financial, Inc. The three options are invested primarily in shares of common stocks of U.S. corporations.

The International Equity Fund has all its assets invested in the Templeton Foreign Fund, a registered mutual fund with its investments in shares of common stock issued by foreign corporations.

The Stable Value Fund is managed by two different portfolio managers. One of these portfolio managers is Norwest Corporation, a bank holding company headquartered in Minneapolis, Minnesota with bank branches in Nebraska. Norwest Corporation manages a pooled fund invested in Guaranteed Investment Contracts and other short term instruments issued by insurance companies, banks, and corporations. The other portfolio manager for the Stable Value Fund is the FirsTier Financial, Inc., which selects and manages the investments in individual Guaranteed Investment Contracts issued by insurance companies. As of December 31, 1994, the Stable Value Fund had 199 participant accounts with a value of $4,067,446.98 equalling 21.5 percent of the total value of the Plan.

Wyoming Trust and Management Company, incorporated in Wyoming and a subsidiary of FirsTier Financial, Inc., is the trustee of the Plan (the Trustee), which provides the services as custodian of Plan assets and as participant recordkeeper.

3. Among the Plan assets in the Stable Value Fund is the GIC issued on March 15, 1991, by Confederation for the principal sum of $500,000.00 to the nominee of FirsTier Financial, Inc. as contract holder for various employee benefit plans.[2] The applicant represents that the GIC is a single-deposit non-benefit-responsive contract, earning interest on the principal at the annual rate of 8.47 percent. The contract provides for annual interest payments, and has a maturity date of March 14, 1996. As of December 31, 1994, the Plan's allocated share of the principal and accumulated interest of the GIC was $257,754.62, representing 6.3 percent of the value of the Stable Value Fund.

The applicant represents that on August 11, 1994, the insurance regulators of Canada seized the assets of Confederation, and on the following day, August 12, 1994, the Ingham County Circuit Court, Lansing, Michigan placed the assets of Confederation located in the United States in conservatorship and rehabilitation, causing Confederation to suspend all payments on its contracts, including the GIC.[3] The applicant further represents that Confederation did not make its scheduled interest payment on the GIC for March 14, 1995, and that it appears unlikely that Confederation will make payment of the principal and interest to the Plan when the GIC matures on March 14, 1996.

4. In order to protect the Plan and its participants and beneficiaries, the Employer proposes to guarantee and advance funds for the payment of the principal amount of the GIC plus interest at the stated contract interest rate of 8.47 percent per annum through December 31, 1994, and thereafter, at the quarterly interest rate earned by the Plan's investment in a diversified Guaranteed Investment Contract fund (the Stable Return Fund) managed by Norwest Corporation.[4] If the conservatorship and rehabilitation of Confederation extends beyond March 14, 2000, the Employer represents that it will make Advances on March 15, 2000, to satisfy any remaining guaranteed amount so that the Plan has complete recovery of the principal amount of the GIC and the earned interest as guaranteed by the Employer.

The applicant represents that Advances will be made only if and when needed by the Plan to satisfy liquidity requirements created by withdrawals such as benefit payments and hardship withdrawals, or transfer

[1] Present members of the Committee are James W. Hewitt, Vice President and General Counsel; Robert E. Miller, Vice President and Director; Charles D. Meyer, Secretary/Treasurer; and Joyce A. Huff, Corporate Benefits Manager.

[2] The GIC was acquired as an investment by the Plan and 3 other employee benefit plans that are sponsored by the Employer and 2 other closely-held employers, respectively, all with some common ownership. Each of the 4 employee benefit plans was allocated a portion of the principal amount of the GIC with the Plan receiving an allocation of $241,450.00 as its portion of the GIC.

[3] The Department notes that the decision to acquire and hold the GIC is governed by the fiduciary responsibility provisions of Part 4, Subtitle B of Title I of the Act. In this regard, the Department is not herein proposing relief for any violation of Part 4 which may have arisen as a result of the acquisition and holding of the GIC by the Plan.

[4] The applicant represents that the quarterly return for the Stable Return Fund for the calendar quarter ended March 31, 1995, and June 30, 1995, was 1.51 percent to 1.5 percent, respectively or annually approximately 6.5 percent to 7 percent, respectively.

requests from participants.[5] Repayment of Advances will be restricted to GIC Proceeds, which are defined by the applicant to consist of cash proceeds obtained by the Plan from Confederation or any successor to Confederation, or from state guaranty funds, or any other third-party making payments with respect to the obligations of Confederation under the GIC. The final Advance will be made by the Employer on March 15, 2000, to ensure that the Plan will have received the principal amount of the GIC and the earned interest as guaranteed by the Employer. The terms of the Advances will be evidenced in a written agreement by and between the Plan and the Employer.

The applicant represents that the proposed transactions will protect the integrity of the Plan as well as protect the participants and beneficiaries of the Plan from any losses that might arise from the GIC if Confederation does not satisfy its obligations. The Employer represents that the transactions will enable the participants and beneficiaries of the Plan to avoid losing confidence in the purpose of the Plan for providing their respective retirement benefits.

5. In summary, the applicant represents that the proposed transaction will satisfy the criteria for an exemption under section 408(a) of the Act because (a) the transactions will enable the Plan to recover all amounts due with respect to the GIC; (b) the Advances will enable the Plan to fund benefit payments, hardship withdrawals, and investment fund transfers within the Plan; (c) repayment of the Advances will be restricted to the GIC Proceeds; (d) repayments will be waived by the Employer to the extent the Advances exceed the GIC Proceeds; and (e) no interest payments or expenses will be incurred by the Plan with respect to the transactions.

FOR FURTHER INFORMATION CONTACT: Mr. C. E. Beaver of the Department, telephone (202) 219–8881. (This is a toll-free number.)

Profit Sharing Plan of Constructors, Inc. (the Plan) Located in Lincoln, Nebraska

[Application No. D–10097]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted the restrictions of sections 406(a) and 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to (1) the proposed extensions of credit in the form of guarantees and advances of funds (the Advances) to the Plan by Constructors, Inc. (the Employer), the sponsor of the Plan, with respect to the Guaranteed Investment Contract No. 64238 (the GIC) issued by Confederation Life Insurance Company of Canada (Confederation); and (2) the repayment of the Advances by the Plan to the Employer; provided that the following conditions are satisfied: (a) All terms and conditions of the transactions are no less favorable to the Plan than those which the Plan would receive in arm's-length transactions; (b) No interest payments or expenses will be incurred by the Plan with respect to the transactions; (c) Repayment of the Advances will be restricted to proceeds from the GIC (GIC Proceeds); (d) Repayment of Advances will be waived by the Employer to the extent that Advances exceed the GIC Proceeds; and (e) All unpaid principal and earned interest of the GIC will be completely paid by the Advances to the Plan by March 15, 2000.

Summary of Facts and Representations

1. The Employer is privately-owned Nebraska corporation that was established in 1948. Its principal place of business located in Lincoln, Nebraska. Employing approximately 300 individuals, the Employer is primarily engaged in the business of highway construction, traffic control, and limestone mining.

2. The Plan is a defined contribution profit sharing plan, providing for individually-directed participant accounts, which is intended to qualify under section 401(a) of the Code. As of December 31, 1994, the Plan had 155 participants and total assets of $4,223,729.49.

The Employer is the administer and named fiduciary as prescribed by the Act. Authority to administer and manage the Plan has been allocated by the Employer to the Retirement Committee (the Committee), which is appointed annually from the officers of the Employer by its Board of Directors.[6] With the respect to the Plan, the duties of the Committee include, *inter alia*, selecting trustees, portfolio managers, and the investment options for the participants, as well as monitoring the investment performance of the assets of the Plan. In performing its duties, the Committee has selected four different funds for the participants to direct the investment of assets in their respective Plan accounts, which include the following: (a) The Bond Fund, (b) the Equity Fund, (c) the International Equity Fund, and (d) the Stable Value Fund.

The Bond Fund is managed by FirsTier Financial, Inc., a regional multi-bank holding company incorporated and headquartered in Nebraska.

The assets of the Equity Fund offers three different investment options: the Washington Mutual Investors Fund; the American Mutual Funds; and E.B. Growth Stock Fund. The first two options are registered mutual funds and the third is a bank collective trust fund managed by FirsTier Financial, Inc. The three options are invested primarily in shares of common stocks of U.S. corporations.

The International Equity Fund has all its assets invested in the Templeton Foreign Fund, a registered mutual fund with its investments in shares of common stock issued by foreign corporations.

The Stable Value Fund is managed by two different portfolio managers. One of these portfolio managers is Norwest Corporation, a bank holding company headquartered in Minneapolis, Minnesota with bank branches in Nebraska. Norwest Corporation manages a pooled fund invested in Guaranteed Investment Contracts and other short term instruments issued by insurance companies, banks, and corporations. The other portfolio manager for the Stable Value Fund is the FirsTier Financial, Inc., which selects and manages the investments in individual Guaranteed Investment Contracts issued by insurance companies. As of December 31, 1994, the Stable Value Fund had 14 participant accounts with a value of $1,536,392.46 equalling 36.4 percent of the total value of the Plan.

Wyoming Trust and Management Company, incorporated in Wyoming and a subsidiary of FirsTier Financial, Inc., is the trustee of the Plan (the Trustee), which provides the services as custodian of Plan assets and as participant recordkeeper.

3. Among the Plan assets in the Stable Value Fund is the GIC issued on March 15, 1991, by Confederation for the principal sum of $500,000.00 to the nominee of FirsTier, Financial, Inc. as contract holder for various employee

[5] The determination as to when advances are needed will be made by the Committee.

[6] Present members of the Committee are James W. Hewitt, Vice President and General Counsel; Robert E. Miller, Vice President and Director; Charles D. Meyer, Secretary/Treasurer; and Joyce A. Huff, Corporate Benefits Manager.

benefit plans.[7] The applicant represents that the GIC is a single-deposit non-benefit-responsive contract, earning interest on the principal at the annual rate of 8.47 percent. The contract provides for annual interest payments, and has a maturity date of March 14, 1996. As of December 31, 1994, the Plan's allocated share of the principal and accumulated interest of the GIC was $96,077.52, representing 6.25 percent of the value of the Stable Value Fund.

The applicant represents that on August 11, 1994, the insurance regulators of Canada seized the assets of Confederation, and on the following day, August 12, 1994, the Ingham County Circuit Court, Lansing, Michigan placed the assets of Confederation located in the United States in conservatorship and rehabilitation, causing Confederation to suspend all payments on its contracts, including the GIC.[8] The applicant further represents that Confederation did not make its scheduled interest payment on the GIC for March 14, 1995, and that it appears unlikely that Confederation will make payment of the principal and interest to the Plan when the GIC matures on March 14, 1996.

4. In order to protect the Plan and its participants and beneficiaries, the Employer proposes to guarantee and advance funds for the payment of the principal amount of the GIC plus interest at the stated contract interest rate of 8.47 percent per annum through December 31, 1994, and thereafter, at the quarterly interest rate earned by the Plan's investment in a diversified Guaranteed Investment Contract fund (the Stable Return Fund) managed by Norwest Corporation.[9] If the conservatorship and rehabilitation of Confederation extends beyond March 14, 2000, the Employer represents that it will make Advances on March 15, 2000, to satisfy any remaining guaranteed amount so that the Plan has complete recovery of the principal amount of the GIC and the earned interest as guaranteed by the Employer.

The applicant represents that Advances will be made only if and when needed by the Plan to satisfy liquidity requirements created by withdrawals such as benefit payments and hardship withdrawals, or transfer requests from participants.[10] Repayment of Advances will be restricted to GIC Proceeds, which are defined by the applicant to consist of cash proceeds obtained by the Plan from Confederation or any successor to Confederation, or from state guaranty funds, or any other third-party making payments with respect to the obligations of Confederation under the GIC. The final Advance will be made by the Employer on March 15, 2000, to ensure that the Plan will have received the principal amount of the GIC and the earned interest as guaranteed by the Employer. The terms of the Advances will be evidenced in a written agreement by and between the Plan and the Employer.

The applicant represents that the proposed transactions will protect the integrity of the Plan as well as protect the participants and beneficiaries of the Plan from any losses that might arise from the GIC if Confederation does not satisfy its obligations. The Employer represents that the transactions will enable the participants and beneficiaries of the Plan to avoid losing confidence in the purpose of the Plan for providing their respective retirement benefits.

5. In summary, the applicant represents that the proposed transaction will satisfy the criteria for an exemption under section 408(a) of the Act because (a) the transactions will enable the Plan to recover all amounts due with respect to the GIC; (b) the Advances will enable the Plan to fund benefit payments, hardship withdrawals, and investment fund transfers within the Plan; (c) repayment of the Advances will be restricted to the GIC Proceeds; (d) repayments will be waived by the Employer to the extent the Advances exceed the GIC Proceeds; and (e) no interest payments or expenses will be incurred by the Plan with respect to the transactions.

FOR FURTHER INFORMATION CONTACT: Mr. C. E. Beaver of the Department, telephone (202) 219–8881. (This is a toll-free number.)

[7] The GIC was acquired as an investment by the Plan and 3 other employee benefit plans that are sponsored by the Employer and 2 other closely-held employers, respectively, all with some common ownership. Each of the 4 employee benefit plans was allocated a portion of the principal amount of the GIC with the Plan receiving an allocation of $90,000.00 as its portion of the GIC.

[8] The Department notes that the decision to acquire and hold the GIC is governed by the fiduciary responsibility provisions of Part 4, Subtitle B of Title I of the Act. In this regard, the Department is not herein proposing relief for any violation of Part 4 which may have arisen as a result of the acquisition and holding of the GIC by the Plan.

[9] The applicant represents that the quarterly return for the Stable Return Fund for the calendar quarter ended March 31, 1995, and June 30, 1995, was 1.51 percent 1.5 percent, respectively or annually approximately 6.5 percent to 7 percent, respectively.

[10] The determination as to when advances are needed will be made by the Committee.

Universal Surety Company Profit Sharing Plan (the Plan) Located in Lincoln, Nebraska

[Application No. D–10098]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted the restrictions of sections 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to (1) the proposed extensions of credit in the form of guarantees and advances of funds (the Advances) to the Plan by Universal Surety Company (the Employer), the sponsor of the Plan, with respect to the Guaranteed Investment Contract No. 64238 (the GIC) issued by Confederation Life Insurance Company of Canada (Confederation); and (2) the repayment of the Advances by the Plan to the Employer; provided that the following conditions are satisfied: (a) All terms and conditions of the transactions are no less favorable to the Plan than those which the Plan would receive in arm's-length transactions; (b) No interest payments or expenses will be incurred by the Plan with respect to the transactions; (c) Repayment of the Advances will be restricted to proceeds from the GIC (GIC Proceeds); (d) Repayment of Advances will be waived by the Employer to the extent that Advances exceed the GIC Proceeds; and (e) All unpaid principal and earned interest of the GIC will be completely paid by the Advances to the Plan by March 15, 2000.

Summary of Facts and Representations

1. The Employer is a privately-owned business that was incorporated in Nebraska during the year of 1947. Its principal place of business is located in Lincoln, Nebraska, where it is engaged in the business of underwriting surety bonds for the construction industry. The Employer currently has 18 employees.

2. The Plan is a defined contribution profit sharing plan, providing for individually-directed participant accounts, which is intended to qualify under section 401(a) of the Code. As of December 31, 1994, the Plan had 19 participants and total assets of $2,472,583.00.

The Employer is the administer and named fiduciary as prescribed by the

Act. Authority to administer and manage the Plan has been allocated by the Employer to the Retirement Committee (the Committee), which is appointed annually from the officers of the Employer by its Board of Directors.[11]

With the respect to the Plan, the duties of the Committee include, *inter alia*, selecting trustees, portfolio managers, and the investment options for the participants, as well as monitoring the investment performance of the assets of the Plan. In performing its duties, the Committee has selected four different funds for the participants to direct the investment of assets in their respective Plan accounts, which include the following: (a) the Bond Fund, (b) the Equity Fund, (c) the International Equity Fund, and (d) the Stable Value Fund.

The Bond Fund is managed by FirsTier Financial, Inc., a regional multi-bank holding company incorporated and headquartered in Nebraska.

The assets of the Equity Fund offers three different investment options: the Washington Mutual Investors Fund; the American Mutual Funds; and E.B. Growth Stock Fund. The first two options are registered mutual funds and the third is a bank collective trust fund managed by FirsTier Financial, Inc. The three options are invested primarily in shares of common stocks of U.S. corporations.

The International Equity Fund has all its assets invested in the Templeton Foreign Fund, a registered mutual fund with its investments in shares of common stock issued by foreign corporations.

The Stable Value Fund is managed by two different portfolio managers. One of these portfolio managers is Norwest Corporation, a bank holding company headquartered in Minneapolis, Minnesota with bank branches in Nebraska. Norwest Corporation manages a pooled fund invested in Guaranteed Investment Contracts and other short term instruments issued by insurance companies, banks, and corporations. The other portfolio manager for the Stable Value Fund is the FirsTier Financial, Inc., which selects and manages the investments in individual Guaranteed Investment Contracts issued by insurance companies. As of December 31, 1994, the Stable Value Fund had 9 participant accounts with a value of $482,008.00 equalling 19.5 percent of the total value of the Plan.

Wyoming Trust and Management Company, incorporated in Wyoming and a subsidiary of FirsTier Financial, Inc., is the trustee of the Plan (the Trustee), which provides the services as custodian of Plan assets and as participant recordkeeper.

3. Among the Plan assets in the Stable Value Fund is the GIC issued on March 15, 1991, by Confederation for the principal sum of $500,000.00 to the nominee of FirsTier, Financial, Inc. as contract holder for various employee benefit plans.[12]

The applicant represents that the GIC is a single-deposit non-benefit-responsive contract, earning interest on the principal at the annual rate of 8.47 percent. The contract provides for annual interest payments, and has a maturity date of March 14, 1996. As of December 31, 1994, the Plan's allocated share of the principal and accumulated interest of the GIC was $53,963.54, representing 11 percent of the value of the Stable Value Fund.

The applicant represents that on August 11, 1994, the insurance regulators of Canada seized the assets of Confederation, and on the following day, August 12, 1994, the Ingham County Circuit Court, Lansing, Michigan placed the assets of Confederation located in the United States in conservatorship and rehabilitation, causing Confederation to suspend all payments on its contracts, including the GIC.[13] The applicant further represents that Confederation did not make its scheduled interest payment on the GIC for March 14, 1995, and that it appears unlikely that Confederation will make payment of the principal and interest to the Plan when the GIC matures on March 14, 1996.

4. In order to protect the Plan and its participants and beneficiaries, the Employer proposes to guarantee and advance funds for the payment of the principal amount of the GIC plus interest at the stated contract interest rate of 8.47 percent per annum through December 31, 1994, and thereafter, at the quarterly interest rate earned by the Plan's investment in a diversified Guaranteed Investment Contract fund (the Stable Return Fund) managed by Norwest Corporation.[14] If the conservatorship and rehabilitation of Confederation extends beyond March 14, 2000, the Employer represents that it will make Advances on March 15, 2000, to satisfy any remaining guaranteed amount so that the Plan has complete recovery of the principal amount of the GIC and the earned interest as guaranteed by the Employer.

The applicant represents that Advances will be made only if and when needed by the Plan to satisfy liquidity requirements created by withdrawals such as benefit payments and hardship withdrawals, or transfer requests from participants.[15] Repayment of Advances will be restricted to GIC Proceeds, which are defined by the applicant to consist of cash proceeds obtained by the Plan from Confederation or any successor to Confederation, or from state guaranty funds, or any other third-party making payments with respect to the obligations of Confederation under the GIC. The final Advance will be made by the Employer on March 15, 2000, to ensure that the Plan will have received the principal amount of the GIC and the earned interest as guaranteed by the Employer. The terms of the Advances will be evidenced in a written agreement by and between the Plan and the Employer.

The applicant represents that the proposed transactions will protect the integrity of the Plan as well as protect the participants and beneficiaries of the Plan from any losses that might arise from the GIC if Confederation does not satisfy its obligations. The Employer represents that the transactions will enable the participants and beneficiaries of the Plan to avoid losing confidence in the purpose of the Plan for providing their respective retirement benefits.

5. In summary, the applicant represents that the proposed transaction will satisfy the criteria for an exemption under section 408(a) of the Act because (a) the transactions will enable the Plan to recover all amounts due with respect to the GIC; (b) the Advances will enable the Plan to fund benefit payments, hardship withdrawals, and investment fund transfers within the Plan; (c) repayment of the Advances will be restricted to the GIC Proceeds; (d) repayments will be waived by the

[11] Present members of the Committee are Thomas A. Tallman, President of the Employer and Leon Harre, Secretary of the Employer.

[12] The GIC was acquired as an investment by the Plan and 3 other employee benefit plans that are sponsored by the Employer and 2 other closely-held employers, respectively, all with some common ownership. Each of the 4 employee benefit plans was allocated a portion of the principal amount of the GIC with the Plan receiving an allocation of $50,550.00 as its portion of the GIC.

[13] The Department notes that the decision to acquire and hold the GIC is governed by the fiduciary responsibility provisions of Part 4, Subtitle B of Title I of the Act. In this regard, the Department is not herein proposing relief for any violation of Part 4 which may have arisen as a result of the acquisition and holding of the GIC by the Plan.

[14] The applicant represents that the quarterly return for the Stable Return Fund for the calendar quarter ended March 31, 1995, and June 30, 1995, was 1.51 percent 1.5 percent, respectively or annually approximately 6.5 percent to 7 percent, respectively.

[15] The determination as to when advances are needed will be made by the Committee.

Employer to the extent the Advances exceed the GIC Proceeds; and (e) no interest payments or expenses will be incurred by the Plan with respect to the transactions.

FOR FURTHER INFORMATION CONTACT: Mr. C.E. Beaver of the Department, telephone (202) 219–8881. (This is a toll-free number.)

Constructors, Inc. 401(k) Plan (the Plan) Located in Lincoln, NE

[Application No. D–10099]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted the restrictions of sections 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to (1) the proposed extensions of credit in the form of guarantees and advances of funds (the Advances) to the Plan by Constructors Inc. (the Employer), the sponsor of the Plan, with respect to the Guaranteed Investment Contract No. 64238 (the GIC) issued by Confederation Life Insurance Company of Canada (Confederation); and (2) the repayment of the Advances by the Plan to the Employer; provided that the following conditions are satisfied: (a) All terms and conditions of the transactions are no less favorable to the Plan than those which the Plan would receive in arm's-length transactions; (b) No interest payments or expenses will be incurred by the Plan with respect to the transactions; (c) Repayment of the Advances will be restricted to proceeds from the GIC (GIC Proceeds); (d) Repayment of Advances will be waived by the Employer to the extent that Advances exceed the GIC Proceeds; and (e) All unpaid principal and earned interest of the GIC will be completely paid by the Advances to the Plan by March 15, 2000.

Summary of Facts and Representations

1. The Employer is a privately-owned Nebraska corporation that was established in 1948. Its principal place of business located in Lincoln, Nebraska. Employing approximately 300 individuals, the Employer is primarily engaged in the business of highway construction, traffic control, and limestone mining.

2. The Plan is a defined contribution profit sharing plan, providing for individually-directed participant accounts, which is intended to qualify under section 401(a) and 401(k) of the Code. As of December 31, 1994, the Plan had 155 participants and total assets of $1,831,751.95.

The Employer is the administer and named fiduciary as prescribed by the Act. Authority to administer and manage the Plan has been allocated by the Employer to the Retirement Committee (the Committee), which is appointed annually from the officers of the Employer by its Board of Directors.[16] With the respect to the Plan, the duties of the Committee include, *inter alia,* selecting trustees, portfolio managers, and the investment options for the participants, as well as monitoring the investment performance of the assets of the Plan. In performing its duties, the Committee has selected four different funds for the participants to direct the investment of assets in their respective Plan accounts, which include the following: (a) the Bond Fund, (b) the Equity Fund, (c) the International Equity Fund, and (d) the Stable Value Fund.

The Bond Fund is managed by FirsTier Financial, Inc., a regional multi-bank holding company incorporated and headquartered in Nebraska.

The assets of the Equity Fund offers three different investment options: the Washington Mutual Investors Fund; the American Mutual Funds; and E.B. Growth Stock Fund. The first two options are registered mutual funds and the third is a bank collective trust fund managed by FirsTier Financial, Inc. The three options are invested primarily in shares of common stocks of U.S. corporations.

The International Equity Fund has all its assets invested in the Templeton Foreign Fund, a registered mutual fund with its investments in shares of common stock issued by foreign corporations.

The Stable Value Fund is managed by two different portfolio managers. One of these portfolio managers is Norwest Corporation, a bank holding company headquartered in Minneapolis, Minnesota with bank branches in Nebraska. Norwest Corporation manages a pooled fund invested in Guaranteed Investment Contracts and other short term instruments issued by insurance companies, banks, and corporations. The other portfolio manager for the Stable Value Fund is the FirsTier Financial, Inc., which selects and manages the investments in individual Guaranteed Investment Contracts issued by insurance companies. As of December 31, 1994, the Stable Value Fund had 59 participant accounts with a value of $599,704.89 equalling 32.7 percent of the total value of the Plan.

Wyoming Trust and Management Company, incorporated in Wyoming and a subsidiary of FirsTier Financial, Inc., is the trustee of the Plan (the Trustee), which provides the services as custodian of Plan assets and as participant recordkeeper.

3. Among the Plan assets in the Stable Value Fund is the GIC issued on March 15, 1991, by Confederation for the principal sum of $500,000.00 to the nominee of FirsTier, Financial, Inc. as contract holder for various employee benefit plans.[17] The applicant represents that the GIC is a single-deposit non-benefit-responsive contract, earning interest on the principal at the annual rate of 8.47 percent. The contract provides for annual interest payments, and has a maturity date of March 14, 1996. As of December 31, 1994, the Plan's allocated share of the principal and accumulated interest of the GIC was $125,968.30, representing 21 percent of the value of the Stable Value Fund.

The applicant represents that on August 11, 1994, the insurance regulators of Canada seized the assets of Confederation, and on the following day, August 12, 1994, the Ingham County Circuit Court, Lansing, Michigan placed the assets of Confederation located in the United States in conservatorship and rehabilitation, causing Confederation to suspend all payments on its contracts, including the GIC.[18] The applicant further represents that Confederation did not make its scheduled interest payment on the GIC for March 14, 1995, and that it appears unlikely that Confederation will make payment of the principal and interest to the Plan when the GIC matures on March 14, 1996.

4. In order to protect the Plan and its participants and beneficiaries, the Employer proposes to guarantee and advance funds for the payment of the

[16] Present members of the Committee are James W. Hewitt, Vice President and General Counsel; Robert E. Miller, Vice President and Director; Charles D. Meyer, Secretary/Treasurer; and Joyce A. Huff, Corporate Benefits Manager.

[17] The GIC was acquired as an investment by the Plan and 3 other employee benefit plans that are sponsored by the Employer and 2 other closely-held employers, respectively, all with some common ownership. Each of the 4 employee benefit plans was allocated a portion of the principal amount of the GIC with the Plan receiving an allocation of $118,000.00 as its portion of the GIC.

[18] The Department notes that the decision to acquire and hold the GIC is governed by the fiduciary responsibility provisions of Part 4, Subtitle B of Title I of the Act. In this regard, the Department is not herein proposing relief for any violation of Part 4 which may have arisen as a result of the acquisition and holding of the GIC by the Plan.

principal amount of the GIC plus interest at the stated contract interest rate of 8.47 percent per annum through December 31, 1994, and thereafter, at the quarterly interest rate earned by the Plan's investment in a diversified Guaranteed Investment Contract fund (the Stable Return Fund) managed by Norwest Corporation.[19] If the conservatorship and rehabilitation of Confederation extends beyond March 14, 2000, the Employer represents that it will make Advances on March 15, 2000, to satisfy any remaining guaranteed amount so that the Plan has complete recovery of the principal amount of the GIC and the earned interest as guaranteed by the Employer.

The applicant represents that Advances will be made only if and when needed by the Plan to satisfy liquidity requirements created by withdrawals such as benefit payments and hardship withdrawals, or transfer requests from participants.[20] Repayment of Advances will be restricted to GIC Proceeds, which are defined by the applicant to consist of cash proceeds obtained by the Plan from Confederation or any successor to Confederation, or from state guaranty funds, or any other third-party making payments with respect to the obligations of Confederation under the GIC. The final Advance will be made by the Employer on March 15, 2000, to ensure that the Plan will have received the principal amount of the GIC and the earned interest as guaranteed by the Employer. The terms of the Advances will be evidenced in a written agreement by and between the Plan and the Employer.

The applicant represents that the proposed transactions will protect the integrity of the Plan as well as protect the participants and beneficiaries of the Plan from any losses that might arise from the GIC if Confederation does not satisfy its obligations. The Employer represents that the transactions will enable the participants and beneficiaries of the Plan to avoid losing confidence in the purpose of the Plan for providing their respective retirement benefits.

5. In summary, the applicant represents that the proposed transaction will satisfy the criteria for an exemption under section 408(a) of the Act because (a) the transactions will enable the Plan to recover all amounts due with respect to the GIC; (b) the Advances will enable the Plan to fund benefit payments, hardship withdrawals, and investment fund transfers within the Plan; (c) repayment of the Advances will be restricted to the GIC Proceeds; (d) repayments will be waived by the Employer to the extent the Advances exceed the GIC Proceeds; and (e) no interest payments or expenses will be incurred by the Plan with respect to the transactions.

FOR FURTHER INFORMATION CONTACT: Mr. C. E. Beaver of the Department, telephone (202) 219–8881. (This is a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 3rd day of October, 1995.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

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[19] The applicant represents that the quarterly return for the Stable Return Fund for the calendar quarter ended March 31, 1995, and June 30, 1995, was 1.51 percent 1.5 percent, respectively or annually approximately 6.5 percent to 7 percent, respectively.

[20] The determination as to when advances are needed will be made by the Committee.

[Prohibited Transaction Exemption 95–93; Exemption Application No. D–10026, et al.]

Grant of Individual Exemptions; Acushnet Company Employee

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Grant of Individual Exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Notices were published in the Federal Register of the pendency before the Department of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, D.C. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of proposed exemption were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29

CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administratively feasible;

(b) They are in the interests of the plans and their participants and beneficiaries; and

(c) They are protective of the rights of the participants and beneficiaries of the plans.

Acushnet Company Employee Savings Plan (the Plan) Located in Fairhaven, MA

[Prohibited Transaction Exemption 95–93; Exemption Application No. D–10026]

Exemption

The restrictions of sections 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the cash sale by the Plan of guaranteed investment contract No. GA–5244 (the GIC) issued by Mutual Life Insurance Company of New Jersey, to the Acushnet Company, a Delaware corporation and a party in interest with respect to the Plan, provided the following conditions are met: (1) The sale is a one-time transaction for cash; (2) the Plan experiences no loss and incurs no expense from the sale; (3) the Plan receives as consideration for the sale the greater of either (a) the fair market value of the GIC on the date of the sale, or (b) the accumulated book value of the GIC as set forth in paragraph 3 of the Notice of Proposed Exemption, with such determination to be made by the State Street Bank and Trust Company, the Plan fiduciary with respect to the GIC.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on August 9, 1995 at 60 FR 40620.

FOR FURTHER INFORMATION CONTACT: Charles S. Edelstein of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

Profit Sharing Plan for Employees of Athens Disposal Co., Ranco Leasing, Covina Disposal Co., and South Pasadena Disposal Co. (the Plan) Located in City of Industry, California

[Prohibited Transaction Exemption 95–94; Exemption Application No. D–10029]

Exemption

The restrictions of sections 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the cash sale on March 24, 1994, for $300,000 (the Sale) of 7,500 shares (the Shares) of common stock issued by Garfield Bank, chartered in California and located in Montebello, California, by the Plan to Athens Disposal Co., Inc., a party in interest with respect to the Plan; provided that (1) the Plan experienced no loss nor incurred any expense from the Sale; and (2) the Plan received as consideration from the Sale an amount that was no less than the fair market value of the Shares on the date of the Sale.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on August 11, 1995, at 60 FR 41126.

New Bedford Institution for Savings Employee Stock Ownership Plan (the Plan) Located in New Bedford, MA

[Prohibited Transaction Exemption 95–95; Exemption Application No. D–10033]

Exemption

The restrictions of sections 406(a), 406 (b)(1) and (b)(2), and 407(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the past acquisition and holding by the Plan of certain stock warrants (the Warrants) in connection with a merger (the Merger) of NBB Bancorp, Inc. (NBB), the parent company of the Plan's sponsor, New Bedford Institution for Savings, with Fleet Financial Group, Inc. (Fleet), provided the following conditions were satisfied: a) the Plan's acquisition and holding of the Warrants occurred in connection with the Merger pursuant to which (i) all shares of common stock of NBB (NBB Stock) were converted, at the election of the shareholder, into cash or shares of common stock of Fleet and (ii) each shareholder received 0.28 Warrants for each share of NBB Stock; b) the acquisition and holding of the Warrants resulted from the independent action of NBB as a corporate entity, and all holders of NBB Stock, including the Plan, were treated in the same manner with respect to the Merger; and c) the Warrants were automatically issued to the Plan, which made no affirmative election to acquire the Warrants.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on August 9, 1995 at 60 FR 40621.

EFFECTIVE DATE: This exemption is effective January 27, 1995.

FOR FURTHER INFORMATION CONTACT: Gary H. Lefkowitz of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

EFFECTIVE DATES: The effective date of this exemption is March 24, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. C. E. Beaver of the Department, telephone (202) 219–8881. (This is not a toll free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions to which the exemptions does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transactional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, D.C., this 3rd day of October, 1995.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 95–24868 Filed 10–5–95; 8:45 am]

BILLING CODE 4510–29–P

LEGAL SERVICES CORPORATION

Notice of Availability of Competitive Grant Funds

AGENCY: Legal Services Corporation.

ACTION: Solicitation for Proposals for the Provision of Civil Legal Services.

SUMMARY: The Legal Services Corporation (LSC or Corporation) is the national organization charged with administering federal funds provided for civil legal services to the poor. The Corporation anticipates that Congress will adopt legislation requiring it to utilize a system of competitive bidding for the award of grants and contracts for calendar year 1996.

The Corporation hereby announces the availability of competitive grant funds and is soliciting grant proposals from interested parties who are qualified to provide effective, efficient, and high quality civil legal services to eligible clients in the fifty states, the District of Columbia, Guam, Micronesia, Puerto Rico, and the U.S. Virgin Islands. Currently, the amount of available funds and the date, terms and conditions of their availability have not been determined.

DATES: Grant proposals must be received at LSC offices by 5:00 p.m. EST, November 3, 1995.

ADDRESSES: Legal Services Corporation/Competitive Grants, 750 First Street, NE., 11th Floor, Washington, DC 20002–4250.

FOR FURTHER INFORMATION CONTACT: Merceria L. Ludgood, Director, Office of Program Services, (202) 336–8900.

SUPPLEMENTARY INFORMATION: LSC is seeking proposals from current LSC recipients and other organizations that have as a purpose the provision of legal assistance to eligible clients; private attorneys; groups of private attorneys or law firms; state or local governments; and substate regional planning and coordination agencies which are composed of substate areas and whose governing boards are controlled by locally elected officials.

The solicitation package, containing the grant application, guidelines, proposal content requirements, and specific selection criteria, is available by contacting the Corporation by letter, phone or FAX. In addition, the solicitation package will be available ''on-line'' and from Handsnet and the LSC Bulletin Board. LSC will not FAX solicitation packages to interested parties, however, solicitation packages may be requested by FAX. The Corporation may be contacted at: (202) 336–8900; FAX: (202) 336–8959; HANDSNET: HN3555; LSC BBS: (202) 336–8950.

Dated: October 3, 1995.

Merceria L. Ludgood,

Director, Office of Program Services.

[FR Doc. 95–24901 Filed 10–5–95; 8:45 am]

BILLING CODE 7050–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Amendment to Charter Names

The Directorate for Education and Human Resources has reorganized to provide a clearer management focus for EHR support for women and girls and call attention to the communications function of the Directorate, to realign systemic activities, and to restructure one division. The reorganization affects the names of a number of Special Emphasis Panels in the directorate. Effective October 1, 1995, the names of the committees listed below will be renamed as follows:

From	To
Special Emphasis Panel in Graduate Education & Research Development (#57).	Special Emphasis Panel in Graduate Education (#57).
Special Emphasis Panel in Research, Evaluation & Dissemination (#1210).	Special Emphasis Panel in Research, Evaluation & Communication (#1210).
Special Emphasis Panel in Systemic Reform (#1765).	Special Emphasis Panel in Educational System Reform (#1765).

All changes are effective October 1, 1995. Charters will be updated to reflect the current organization as they are renewed.

Dated: September 29, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24838 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Undergraduate Education; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Undergraduate Education.

Date and Time: January 24, 1996 7:30 p.m. to 9:00 p.m., January 25, 1996 8:30 a.m. to 5:00 p.m., January 26, 1996 8:30 a.m. to 5:00 p.m., January 27, 1996 8:30 a.m. to 3:00 p.m., January 31, 1996 7:30 p.m. to 9:00 p.m., February 1, 1996 8:30 a.m. to 5:00 p.m., February 2, 1996 8:30 a.m. to 5:00 p.m., February 3, 1996 8:30 a.m. to 3:00 p.m.

Place: Doubletree National Airport Hotel, 300 Army/Navy Drive, Arlington, VA. 22202.

Type of Meeting: Closed.

Contact Person: Dr. Daniel Hodge, Program Director, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone: (703) 306–1669.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate unsolicited proposals submitted to the Instrumentation and Laboratory Improvement (ILI) Program.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24839 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

President's Committee on the National Medal of Science; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: President's Committee on the National Medal of Science (#1182).

Date and Time: Tuesday, October 24, 1995, 9:00 a.m.–3:00 p.m.

Place: Room 320, National Science Foundation, 4201 Wilson Blvd., Arlington, VA.

Type of Meeting: Closed.

Contact Person: Mrs. Susan E. Fannoney, Program Manager, Room 1220, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: 703/306–1096.

Purpose of Meeting: To provide advice and recommendations to the President in the selection of the National Medal of Science recipients.

Agenda: To review and evaluate nominations as part of the selection process for awards.

Reason for Closing: The nominations being reviewed include information of a personal nature where disclosure would constitute unwarranted invasions of personal privacy. These matters are exempt under 5 U.S.C. 552b(c)(6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24840 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Advisory Panel for Instrumentation & Instrument Development; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name and Committee Code: Advisory Panel for Instrumentation and Instrument Development (#1215).

Date and Time: October 24–25, 1995, 8:30 a.m.–5:00 p.m.

Place: NSF, 4201 Wilson Boulevard, Arlington, VA, Rm. 370.

Type of Meeting: Closed.

Contact Person: John Cross, Program Director, Biological Instrumentation and Instrument Development, Room 615, National Science Foundation, Telephone: (703) 306–1472.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Instrumentation and Instrument Development proposals for Instrument Development for Biological Research as part of the selection process for award.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24841 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Advisory Panel for Physiology and Behavior; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting.

Name: Advisory Panel for Physiology and Behavior (#1160).

Date and Time: October 23 and 24, 1995, 8:00 a.m.–6:00 p.m.

Place: Room 390, 4201 Wilson Boulevard, Arlington, Virginia 22230.

Type of Meeting: Part-Open.

Contact Person: Dr. Elvira Doman and Dr. John Fray, Program Directors, Integrative Animal Biology, Division of Integrative Biology and Neuroscience, Room 685, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230. Telephone: (703) 306–1421.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: Open Session: October 24, 2:00 p.m.–3:00 p.m.: Discussion with Dr. Mary Clutter, Assistant Director, Directorate for Biological Sciences. To discuss research trends and opportunities in biology. Closed Session: October 23, 8:00 a.m.–6:00 p.m., October 24, 8:00 a.m.–2:00 p.m., 3:00p.m.–6:00 p.m.. To review and evaluate Integrative Animal Biology proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24842 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Advisory Panel for Genetics and Nucleic Acids; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Advisory Panel for Genetics and Nucleic Acids (1149) (Panel A).

Date and Time: Thursday, Oct. 26, through Friday, Oct. 27, 1995, at 8:30 a.m. to 5:00 p.m.

Place: Room 360, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. S. Porter Ridley (Program Manager) or Dr. Philip Harriman (Program Director) for Microbial Genetics, Division of Molecular and Cellular Biosciences, Room 655, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230 (703) 306–1441.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate research proposals submitted to the Microbial Genetics Program as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24843 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Advisory Panel for Biochemistry and Molecular Structure and Function; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Advisory Panel for Biochemistry and Molecular Structure and Function—(1134) (Panel C).

Date and Time: Thursday and Friday, October 26 & 27, 1995 8:30 a.m. to 5:00 p.m.

Place: Room 320, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 2230.

Type of Meeting: Closed.

Contact Persons: Dr. Rona Hirschberg, Program Director, and Ms. Brenda Flam, Program Manager, Metabolci Biochemistry, Room 655, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230, (703/306–1443).

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate research proposals submitted to the Metabolic Biochemistry Program as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Bebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24844 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Advisory panel for Cell Biology; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Advisory panel for Cell Biology (1136)—(Panel B).

Date and Time: October 25–27, 1995, 8:30 a.m. to 6:00 p.m.

Place: Room 380, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Eve Barak or Dr. Randolph Addison, Program Directors for the Cell Biology Program, National Science Foundation, Room 655 South, Arlington, VA 22230, Telephone: 703/306–1442.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate research proposals submitted to the Cellular

Organization Program as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24845 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Advisory Panel for Biochemistry and Molecular Structure and Function; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Advisory Panel for Biochemistry and Molecular Structure and Function—(1134) (Panel B).

Date and Time: Monday, Tuesday, and Wednesday, October 23, 24, & 25, 1995, 8:30 A.M. to 6:00 P.M.

Place: National Science Foundation, 4201 Wilson Blvd., Room 340, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Persons: Dr. Kamal Shukla and Dr. Martin Poe, Program Directors for Molecular Biophysics, Room 655, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230, (703/306–1444).

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate research proposals submitted to the Molecular Biophysics Program as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24846 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Bioengineering and Environmental Systems; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Bioengineering and Environmental Systems (No. 1189).

Date and Time: October 27, 1995; 8:30 a.m.–5:00 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Room 565, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Gilbert B. Devey, Program Director, Biomedical Engineering and Research to Aid Persons with Disabilities, Division of Bioengineering and Environmental Systems, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone (703) 306–1318.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24847 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Proposal Review Panel in Earth Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Proposal Review Panel in Earth Sciences (1569).

Date and Time: October 25–27, 1995; 8:30 a.m. to 6:00 p.m.

Place: Scripps Institution of Oceanography, La Jolla, CA 92093.

Type of Meeting: Closed.

Contact Person: Dr. Daniel F. Weill, Program Director, Instrumentation & Facilities Program, Division of Earth Sciences, Room 785, National Science Foundation, Arlington, VA 22230, (703) 306–1558.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Instrumentation & Facilities proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24848 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Mathematical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name and Committee Code: Special Emphasis in Mathematical Sciences (#1204).

Date and Time: October 26–27, 1995, 8:30 AM until 5:00 PM.

Place: Room 1020, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of meeting: Closed.

Contact Person: Keith Crank, Program Director, Division of Mathematical Sciences, Room #1025 National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (703) 306–1885.

Purpose of meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Research Experiences for Undergraduates proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24850 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Advisory Panel for Neuroscience; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting;

Name: Advisory Panel for Neuroscience (1158).

Dates and Time: October 27 & 28, 1995; 8:30 a.m.–5:00 p.m.

Place: Room 680, 4201 Wilson Boulevard, Arlington, VA.

Type of Meeting: Part-Open.

Contact Persons: Dr. Otto Friesen, Program Director, Behavioral Neuroscience; Dr. Carol Colby, Program Director, Computational Neuroscience; Division of Integrative Biology

and Neuroscience, Room 685, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230; Telephone: (703) 306–1416.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Minutes: May be obtained from the contact persons listed above.

Agenda: Open Session: October 27, 1995; 1:30 p.m. to 2:30 p.m., To discuss goals and assessment procedures. Closed Session: October 27, 1995; 9:00 a.m. to 1:30 p.m.; 2:30 p.m. to 5:00 p.m.; October 28, 1995; 9:00 a.m. to 5:00 p.m.; To review and evaluate Behavioral and Computational Neuroscience proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24851 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Engineering Education and Centers; Notice of Meeting In Accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as Amended), the National Science Foundation Announces the Following Meeting

Name and Committee Code: Special Emphasis Panel in [Special Emphasis Panel in] Engineering Education Centers (#173).

Date and Time: October 26, 1995, 8:30 a.m.–5:00 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Conference Rm 580, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Sue Kemnitzer, Deputy Division, Engineering Education and Centers Division, National Science Foundation, 4201 Wilson Boulevard, Rm 585, Arlington, VA 22230, (703) 306–1380.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate proposals submitted to the Research Experiences for Undergraduates Program as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24852 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Advisory Committee for Education and Human Resources, Subcommittee on Undergraduate Education; Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meetings:

Name: Subcommittee on Undergraduate Education.

Dates and Time: October 23, 1995, 8:15 AM to approximately 1:00 PM, October 25, 1995, 8:15 AM to approximately 2:00 PM, November 1, 1995, 8:15 AM to approximately 1:00 PM.

Place: National Science Foundation, Room 1235, 4201 Wilson Blvd., Arlington, VA 22230.

Type of Meeting: Open.

Contact Person: Myles G. Boylan, Executive Secretary, Directorate for Education and Human Resources, National Science Foundation Room 835, Arlington, VA 22230, (703) 306–1681.

Purpose of Subcommittee: To conduct a review of undergraduate education in science, mathematics, engineering, and technology, and to provide advice and recommendations to Advisory Committee.

Agenda: October 23: Disciplinary Perspectives of Leaders in Education; October 25: Institutional Perspectives of College and University Leaders; November 1: Views of Employers on Capabilities of Undergraduate Students Entering the Work Force.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24853 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

DOE/NSF Nuclear Science Advisory Committee; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Date and Time: October 25, 1995 from 5:30 p.m. to 7:30 p.m.; October 25, 1995 from: 8:30 p.m. to 10:30 p.m.

Place: University Club, Indiana Memorial Union, Indiana University, 900 East Seventh Street, Bloomington, IN 47405.

Type of Meeting: Open.

Contact Person: John W. Lightbody, Program Director for Nuclear Physics, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1890.

Minute: May be obtained from the contact person listed above.

Purpose of Meeting: To advise the National Science Foundation and the Department of Energy on scientific priorities within the field of basic nuclear science research.

Agenda:

* Status of the NSAC Long Range Plan.
* Status of DOE Nuclear Physics Program, implications of Long Range Plan recommendations, and subsequent discussion by NSAC (D. Hendrie, DOE).
* Status of NSF Nuclear Physics Program, implications of Long Range Plan recommendations, and subsequent discussion by NSAC (J. Lightbody, NSF).
* Public Comment(*).
* Persons wishing to speak should make arrangements through the Contact Person identified above.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24854 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Advisory Panel for Neuroscience; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting;

Name: Advisory Panel for Neuroscience (1158).

Dates and Time: October 23–24, 1995, 9:00 a.m. to 5:00 p.m.

Place: National Science Foundation, Rm 320, 4201 Wilson Boulevard, Arlington, VA.

Type of Meeting: Part-Open.

Contact Person: Dr. James Koenig, Program Director, Neuronal and Glial Mechanisms; Division of integrative Biology and Neuroscience, Room 685, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230; Telephone: (703) 306–1424.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Minutes: May be obtained from the contact person listed above.

Agenda: Open Session: October 24, 1995; 2:30 p.m. to 3:30 p.m., To discuss research trends and opportunities in Neuronal and Glial Mechanisms. Closed Session: October 23, 1995; 9:00 a.m. to 5:00 p.m; October 24, 1995, 9:00 a.m. to 2:30 p.m., 3:30 p.m. to 5:00 p.m. To review and evaluate Neuronal and Glial mechanisms proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 2, 1995.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 95–24849 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

Statement of Organization; Amendment

AGENCY: National Science Foundation.

ACTION: Notice of amendment to the NSF Statement of Organization, Functions, and Delegations of Authority.

SUMMARY: The Directorate for Education and Human Resources has reorganized to provide a clearer management focus for EHR support for women and girls and call attention to the communications functions of the directorate, to realign systematic activities, and to restructure one division. The new organizational structure is outlined below:

EFFECTIVE DATE: September 3, 1995.

FOR FURTHER INFORMATION CONTACT: M. Rebecca Winkler, National Science Foundation, Division of Human Resource Management, 4201 Wilson Boulevard, Room 315, Arlington, Virginia 22230, telephone 703–306–1181.

SUPPLEMENTARY INFORMATION: The following programs are relocated from the Division of Graduate Education and Research Development (GERD) to the Division of Human Resources Development (HRD):

Faculty Awards for Women Program
Visiting Professorships for Women Program

- The Experimental Program to Stimulate Competitive Research (EPSCoR) is taken out of the Office of Systemic Reform (OSR) and is established as an Office within the Office of the Assistant Director.
- Organizational names changes are:

From	To
Division of Graduate Education & Research Development (GERD).	Division of Graduate Education (DGE).
Division of Research, Evaluation & Dissemination (RED).	Division of Research, Evaluation & Communication (REC).
Office of Systemic Reform (OSR).	Office of Educational System Reform (ESR).

The Division of Elementary, Secondary and Informal Education (ESIE) was restructured to reflect Sections rather than Units.

[For the National Science Foundation Statement of Organization, see the Federal Register of February 8, 1993, 58 FR 7587–7595; May 27, 1993, 58 FR 30819; and May 2, 1994, 58 FR 22690]

Dated: September 30, 1995.

M. Rebecca Winkler,

Management Analyst.

[FR Doc. 95–24837 Filed 10–5–95; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–302]

Exemption; Florida Power Corporation, Crystal River Nuclear Generating Plant Unit 3

I

Florida Power Corporation (the licensee) is the holder of Facility Operating License No. DPR–72, which authorizes operation of the Crystal River Nuclear Generating Plant Unit 3 (CR–3). The license provides, among other things, that the licensee is subject to all rules, regulations, and orders of the Commission now or hereafter in effect.

The facility is of a pressurized water reactor type and is located in Citrus County, Florida.

II

Pursuant to Title 10 Code of Federal Regulations Part 50 (10 CFR 50), Appendix A, ''General Design Criteria for Nuclear Power Plants,'' Criterion 16, ''Containment design,'' ''Reactor containment and associated systems shall be provided to establish an essentially leak-tight barrier against the uncontrolled release of radioactivity to the environment and to assure that the containment design conditions important to safety are not exceeded for as long as postulated accident conditions require.'' 10 CFR 50.54(o) states that ''Primary reactor containments for water cooled power reactors shall be subject to the requirements set forth in Appendix J to this part.'' 10 CFR 50, Appendix J, sets forth requirements for periodic verification by tests of the leak-tight integrity of the primary reactor containment and establish the acceptance criteria for such tests to satisfy general design criterion 16 of the Commission's regulations. 10 CFR 50, Appendix J, Paragraph III.D.1, specifies a set of three integrated leak rate tests (ILRT or Type A test) to be performed at approximately equal intervals during each 10-year service period. Such tests are to be limited to periods when the plant is non-operational and secured in the shutdown condition under an administrative control and in accordance with the safety procedures defined in the license.

For CR–3, the next available opportunity for performing the ILRT would be in spring 1996. The licensee requested a one-time interval extension for the ILRT by approximately 24 months from the spring 1996 refueling outage to the spring 1998 refueling outage. The licensee indicated that approval of its request would save over two million dollars and reduce personnel radiation exposure. An exemption from 10 CFR 50, Appendix J, Paragraph III.D.1, is needed to permit the licensee to defer the ILRT.

By letter dated May 19, 1995, as supplemented August 8, 1995, the licensee submitted its exemption request for this purpose.

III

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health and safety, and are consistent with the common defense and security; and (2) when special circumstances are present. Special circumstances are present whenever, according to 10 CFR 50.12(a)(2)(ii), ''Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule * * *'' The underlying purpose of 10 CFR 50, Appendix J, Paragraph III.D.1., is to assure that periodic surveillance of reactor containment penetrations is performed so that proper maintenance and repairs are made during the service life of the containment, and leakage through the primary reactor containment shall not exceed allowable leakage rate values as specified in the technical specifications (TS) or associated bases.

IV

In support of its exemption request, the licensee submitted information pertaining to Type A, and local leak rate (LLRT or Types B and C) testing history, structural capability, and risk assessment to demonstrate that the proposed exemption would not present an undue risk to the public health and safety and would be consistent with the common defense and security, and would be authorized by law. The licensee indicates that the Type A testing frequency of Appendix J is not necessary to achieve the underlying purpose of the regulation and thus

special circumstances required by 10 CFR 50.12(a)(2)(ii) apply to this situation.

The CR–3 containment is a reinforced concrete structure with a cylindrical wall, a flat foundation mat, and a shallow dome roof. The cylinder wall is prestressed with a post-tensioning system in the vertical and horizontal directions. The dome roof is prestressed using a three-way post-tensioning system. The inside surface of the containment has a carbon steel liner to ensure a high degree of leak-tightness during operating and accident conditions. The liner is anchored to the concrete to ensure composite action with the concrete shell. Piping penetrations have been designed to ensure that the liner would not be breached due to rupture of any process pipe. The containment is designed with an allowable leakage rate of 0.25% of containment air weight per day (L_a) at the calculated maximum allowable containment pressure (P_a) of 54.2 psig resulting from the limiting design basis accidents.

The historical Type A test results as set forth in the exemption request demonstrate that CR–3 has a low-leakage containment. The current 10-year inservice inspection and inservice testing service period is the second service period and started in March 1987 and ends in March 1997. During this service period, the licensee performed one ILRT in November 7, 1991. A prior ILRT conducted in November 1987 was counted as the third test of the first 10-year interval and therefore, the licensee did not take credit for the November 1991 test for the current interval. These two ILRTs which have been performed during the last seven years have shown acceptable containment leakage rates. There have been no permanent or temporary modifications to the containment structure, liner or penetrations since the last two Type A tests, and no future modifications are planned prior to the 1998 refueling outage that could adversely affect the Type A test results.

The licensee will continue to be required to conduct the Type B and C local leak rate tests, which are in general the principal means of detecting containment leakage paths, with the Type A tests confirming the Type B and C test results. Types B and C testing history at CR–3 shows that the overall combined as-found leakage has been less than the allowed combined leakage rate of 0.6 L_a (266,431 SCCM) at the calculated maximum peak containment pressure as specified in Appendix J. Successful performance of Types B and C testing demonstrates the leak-tightness of the penetrations and associated components and provides a high degree of assurance that the overall Type A leakage rate would remain satisfactory while this exemption is in effect. The licensee has stated that it will perform the general containment inspection, although it is required by Appendix J (Section V.A.) to be performed only in conjunction with Type A tests. The NRC staff considers that these inspections, though limited in scope, provide an important added level of confidence in the continued integrity of the containment boundary.

The purpose of containment leak testing is to detect containment leakage which could be the result of failures (active or passive) before an accident occurs. Containment leakage caused by degradation of sealing material within containment penetrations and containment isolation components will continue to be effectively measured by the Type B and C testing programs. The Type A tests are only confirmatory of the results of the Type B and C test results. The only potential failures not covered by Types B and C testing are failures of the containment due to structural deterioration because of parameters such as pressure or temperature. However, structural deterioration would require longer than the proposed period for the exemption.

There are no mechanisms that would adversely affect the structural capability of the containment, which is the only leakage mode not captured by the Type B and C testing that will be performed. Absent actual accident conditions, structural deterioration of containment due to temperature, radiation, chemical, or other such effects is a gradual phenomenon requiring periods of time well in excess of the proposed interval extension and is subject to detection by periodic visual inspections. At CR–3, there has been no evidence of structural deterioration that would impact structural integrity or leak tightness. Other than postulated accident conditions, the only over-pressure challenge to containment is the integrated leak rate test itself. Thus, there is significant assurance that the extended interval between Type A tests in concert with Type B and C testing will continue to provide adequate verification of the leak tight integrity of the containment. The proposed one-time change in Type A leakage test frequency only affects the length of time that the containment could be in an undetected failed state as a result of a failure. As part of the CR–3 Individual Plant Examination (IPE) program, the risk of losing containment integrity is considered negligible compared to other risks such as those resulting from small break loss of coolant accidents or station blackout.

Draft NUREG–1493, which provides the technical justification for the ongoing Appendix J rulemaking effort (including a 10-year test frequency), has shown that essentially all containment leakage can be detected by LLRTs (Type B and C). According to results given in NUREG–1493, only 5 ILRT failures out of 180 ILRT reports that covered 110 individual reactors and approximately 770 years of operating history, were found that local leak rate testing could not have detected. Therefore, it is unlikely that this one-time exemption for the performance of Type A testing at CR–3 would result in significant degradation of the overall containment integrity.

In summary, the testing history, structural capability of the containment, and the risk assessment discussed previously establish that (1) CR–3 has had acceptable containment leakage rate test results, (2) the structural integrity of containment is assured, and (3) there is negligible risk impact in changing the Type A test schedule on a one-time basis.

Therefore, application of the regulation in this particular circumstance would not serve, nor is it necessary to achieve, the underlying purpose of the rule, and the exemption request meets the requirements of 10 CFR 50.12.

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), an exemption is authorized by law, will not endanger life or property or common defense and security, and is otherwise in the public interest. Therefore, the Commission hereby grants Florida Power Corporation a one-time exemption from those requirements of 10 CFR 50, Appendix J, relating to containment overall leak rate test and allows deferring the performance of a Type A test from the spring 1996 to the spring 1998 refueling outage, provided that the general containment inspection is performed during the spring 1996 outage. Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not result in any significant adverse environmental impact (60 FR 46320).

Dated at Rockville, Maryland, this 29th day of September 1995.

For the Nuclear Regulatory Commission.

Steven A. Varga,

Director, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 95–24895 Filed 10–5–95; 8:45 am]

BILLING CODE 7590–01–P

[Docket Nos. 50–387 and 50–388]

Pennsylvania Power and Light Company; Notice of Withdrawal of Application for Amendment to Facility Operating Licenses

The U.S. Nuclear Regulatory Commission (the Commission) has granted a request by Pennsylvania Power and Light Company (the licensee) to withdraw its November 11, 1994 application for proposed amendment to Facility Operating License Nos. NPF–14 and NPF–22, for Susquehanna Steam Electric Station, Units 1 and 2, located in Luzerne County, Pennsylvania.

The proposed amendment would have revised the Technical Specifications (TS) to extend the main turbine valve surveillance test interval from a weekly basis to no greater that 92 days for all main turbine stop, control, and combined intermediate valves.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the Federal Register on December 21, 1994 (59 FR 65821). However, by letter dated August 21, 1995, the licensee withdrew the proposed change.

For further details with respect to this action, see (1) the application for amendment dated November 11, 1994, and the licensee's letter dated August 21, 1995, which withdrew the application for license amendment. The above documents are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701.

Dated at Rockville, Maryland, this 2nd day of October 1995.

For the Nuclear Regulatory Commission.

Chester Poslusny,

Senior Project Manager, Project Directorate I–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 95–24896 Filed 10–5–95; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–26384]

Filings Under the Public Utility Holding Company Act of 1935, as Amended (''Act'')

September 29, 1995.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by October 23, 1995, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Energy Initiatives, Inc., et al. (70–7727)

Energy Initiatives, Inc. (''EII''), One Upper Pond Road, Parsippany, New Jersey 07054, a nonutility subsidiary of General Public Utilities Corporation (''GPU''), a registered holding company, and GPU (both, ''Applicants''), 100 Interpace Parkway, Parsippany, New Jersey 07054, have filed a post-effective amendment under sections 6(a), 7, 9(a), 10 and 12(b) of the Act and rules 45, 52, 53 and 54 thereunder to their application-declaration filed under sections 6(a), 7, 9(a), 10, 12(b), 12(c) and 13(b) of the Act and rules 45, 50, 51, 90 and 91 thereunder.

By orders dated June 26, 1990, December 18, 1992, September 12, 1994, December 28, 1994 and June 14, 1995 (HCAR Nos. 25108, 25715, 26123, 26205 and 26307, respectively) (collectively, ''Orders''), EII was authorized to engage in preliminary project development and administrative activities (''Project Activities'') in connection with its investments in: (i) qualifying cogeneration facilities (''QFs''), as defined in the Public Utility Regulatory Policies Act of 1978, as amended (''PURPA''), located anywhere in the United States, (ii) small power production facilities (also ''QFs''), as defined by PURPA, (iii) exempt wholesale generators (''EWG''), and (iv) foreign utility companies (''FUCOs'').

The Orders also authorized GPU from time to time through December 31, 1997 to: (i) make capital contributions to EII; (ii) enter into letter of credit reimbursement agreements (''Reimbursement Agreements'') and guarantees or similar obligations (''Guarantees'') to secure EII's agreement with any person (including without limitation project lenders) in connection with EII's Project Activities and the acquisition of ownership or participation interests in projects; (iii) guarantee the securities or other obligations of EWGs and FUCOs; and (iv) assume liabilities of EWGs and FUCOs. The aggregate amount which GPU was authorized to contribute to EII, together with the outstanding face or principal amount of the Reimbursement Agreement and Guarantee obligations, and liabilities assumed, could not exceed $200 million (''Contribution Cap''). The Orders also authorized EII to enter into Reimbursement Agreements and Guarantees, and to assume liabilities of EWGs and FUCOs, in an aggregate amount of up to $30 million from time to time through December 31, 1997 (''EII Guarantee Cap'').

The Orders further authorized EII to issue, sell and renew from time to time through December 31, 1997 its promissory notes evidencing short-term borrowings from commercial banks and other financial institutions, in an aggregate principal amount at any time outstanding (together with the aggregate amount of obligations outstanding under Reimbursement Agreements and Guarantees entered into, and liabilities assumed, by EII) not exceeding the EII Guarantee Cap. In addition, the Orders authorized GPU to guarantee such promissory notes (''Note Guarantees'').

As of June 30, 1995, GPU made cash capital contributions to EII, and had outstanding Reimbursement Agreement and Guarantee obligations, and liabilities assumed, of approximately $29 million, pursuant to the December 28, 1994 Order. As of such date EII had not entered into any Reimbursement Agreements or Guarantees or assumed any liabilities pursuant to the Orders.

GPU and EII now propose to: (i) increase the Contribution Cap to $500

million; (ii) expand the purposes for which GPU may enter into Guarantees, subject to the limitation of the Contribution Cap, to include Guarantees of bank or other borrowings by EII, as described below; (iii) relinquish the authorization with respect to GPU Note Guarantees; and (iv) increase the EII Guarantee Cap to $50 million.[1]

The term of each Guarantee, and any letter of credit (''L/C'') backed by a GPU or EII Reimbursement Agreement, would not exceed 25 years. Drawings under each L/C would bear interest at not more than 5% above the prime rate as in effect from time to time, and L/C fees would note exceed 1% annually of the face amount of the L/C.

Borrowings by EII with respect to which GPU may issue a Guarantee would be in the form of bank or other institutional borrowings (''Institutional Borrowings''), commercial paper (''Commercial Paper''), or notes sold in a private placement (''Notes'') under the Securities Act of 1933 (''1933 Act''). Institutional Borrowings would mature not later than five years after issuance, bear interest at a rate not in excess of (i) 250 basis points above the greater of (A) the lending bank's or other recognized prime rate and (B) 50 basis points above the federal funds rate, (ii) 400 basis points above the specified London Interbank Offered Rate plus any applicable reserve requirement, or (iii) a negotiated fixed rate which, in any event, would not exceed 500 basis points above the 30 year ''current coupon'' treasury bond rate. Such borrowings would be prepayable only to the extent provided therein. In addition, such borrowings would be unsecured and would not be made as part of any public offering. Borrowings may be made pursuant to loan agreements or lines of credit established by EII with commercial banks or other institutions. Such agreements or lines of credit may include a letter of credit facility. Drawings on an L/C would bear interest at rates not exceeding the interest rates for Institutional Borrowings (described above), and EII may be required to pay the issuing bank a letter of credit fee not exceeding 1% per annum of the face amount of the L/C.

Commercial Paper sold by EII would be issued in denominations of $100,000 or multiples thereof with maturities of up to 270 days and would not be prepayable prior to maturity. Commercial Paper would be sold directly to one or more commercial paper dealers at a discount rate prevailing at the date of issuance for commercial paper of comparable quality and of the particular maturity sold by other issuers of commercial paper. Commercial Paper will be reoffered by the purchasing dealer or dealers to institutional investors at a discount of not more than ⅛ of 1% per annum less than the prevailing discount rate to EII.

The Commercial Paper dealers will offer and resell the Commercial Paper to not more than a total of 200 of their respective customers, identified and designated in a non-public list (''Closed List'') prepared by each such dealer in advance for this purpose.

EII may also utilize the services of one or more commercial paper placement agents (''Placement Agent'') through whom they would sell their Commercial Paper directly to one or more institutional investors included on the Placement Agent's Closed List (as it may be amended) which would not exceed 200 such investors. The Placement Agent would arrange for the sale of Commercial Paper and would be compensated for its services out of the discount on the sale.

Notes would be sold by EII directly to one or more financial institutions in a private placement, or to one or more underwriters for resale to qualified institutional buyers pursuant to rule 144A under the 1933 Act. The Notes would be unsecured, have maturities not exceeding 20 years, and would bear interest at a fixed rate not to exceed the sum of the yield to maturity of an actively traded U.S. treasury bond with a maturity equal to the maturity of the Notes plus 600 basis points. A placement agent would arrange for the sale of the Notes issued in a private placement, and would be compensated for its services by payment of a fee not to exceed 3% of the face amount of the Notes issued and sold. EII would compensate an underwriter in a rule 144A sale of Notes through a discount on the sale.

The proceeds from the Institutional Borrowings, Commercial Paper or Notes as proposed herein will be used by EII to finance its business, including to finance the acquisition of securities of EWGs and FUCOs. EII believes that having the flexibility to provide a GPU Guarantee will enable it to reduce the interest costs of these borrowings.

The authorization requested herein with respect to Guarantees of Institutional Borrowings, Commercial Paper and Notes is intended to supersede and replace the authorization heretofore granted in respect of GPU Note Guarantees. Accordingly, effective upon receipt of the supplemental Commission order requested herein, GPU would relinquish any remaining authorization in respect of Note Guarantees.

Allegheny Power System, Inc., et al. (70–7888)

Allegheny Power System, Inc. (''Allegheny''), Tower Forty Nine, 12 East 49th Street, New York, New York 10017, a registered holding company, Allegheny Power Service Corporation, 800 Cabin Hill Drive, Greensburg, Pennsylvania 15601, Allegheny's service company subsidiary, three electric utility subsidiary companies of Allegheny—(i) Monongahela Power Company (''Monongahela''), 1310 Fairmont Avenue, Fairmont, West Virginia 26554, (ii) The Potomac Edison Company (''Potomac Edison''), 10435 Downsville Pike, Hagerstown, Maryland 21740, and (iii) West Penn Power Company (''West Penn''), 800 Cabin Hill Drive, Greensburg, Pennsylvania 15601, and Allegheny Generating Company (''AGC''), Tower Forty Nine, 12 East 49th Street, New York, New York 10017, and electric public utility subsidiary of Monongahela, Potomac Edison and West Penn (collectively, ''Applicants'') have filed a post-effective amendment to their application-declaration filed under sections 6(a), 7, 9(a), 10 and 12(b) of the Act and rules 45, 53 and 54 thereunder.

By order dated January 29, 1992 (HCAR No. 25462) (''January 1992 Order''), the Commission authorized the issuance on the part of Monongahela of short-term bank notes and of commercial paper through December 31, 1993. The authorization was for an aggregate principal amount of up to $86 million.

By order dated February 28, 1992 (HCAR No. 25481) (''February 1992 Order''), the Commission authorized: (i) the issuance of short-term bank notes on the part of Allegheny, Potomac Edison and West Penn; (ii) the issuance and sale of commercial paper on the part of Allegheny, Potomac Edison, West Penn and AGC; (iii) a revolving credit agreement for AGC; and (iv) the establishment of a money pool for the Allegheny system (''Money Pool''). The authorization extended through December 31, 1993. In addition, the February 1992 Order limited the aggregate principal amount of short-term financing to $165 million for Allegheny, $94 million for Potomac Edison, $147 million for West Penn and $150 million for AGC. The commercial paper issued by AGC was to be backed by a $150 million revolving credit

[1] Pursuant to amendments to rules 52(b) and 45(b)(4) effective June 28, 1995, cash capital contributions by GPU to EII are now exempt from section 9(a) and rule 45, and borrowings by EII pursuant to Notes are now exempt from section 6(a); accordingly, such transactions are no longer subject to the limitation of the Contribution Cap and the EII Guarantee Cap, respectively.

agreement between AGC and a group of banks. The February 1992 Order also authorized Monongahela, Potomac Edison and West Penn to guarantee, through June 30, 1993, the amounts that AGC borrowed under the revolving credit agreement.

By order dated July 14, 1992 (HCAR No. 25581), Monongahela, Potomac Edison and West Penn were authorized to guarantee the amounts that AGC borrowed under the revolving credit agreement through December 31, 1993.

By order dated November 5, 1993 (HCAR No. 25919) (''November 1993 Order''), Applicants were authorized to continue their short-term financing from December 31, 1992 through December 31, 1995.

Applicants now propose to continue the authorization granted by the November 1993 Order from December 31, 1995 through December 31, 1997, subject to the changes described below. In all other respects, Applicants' proposals remain the same as authorized by prior Commission orders.

Allegheny, Monongahela, Potomac Edison, West Penn, and AGC hereby request that, from December 31, 1995 to December 31, 1997, they be authorized to issue short-term debt in aggregate amounts not to exceed the following amounts outstanding at any one time for each of the following Applicants: Allegheny—$165 million; Monongahela—$100 million; Potomac Edison—$115 million; West Penn—$170 million; AGC—$175 million.

Allegheny, Monongahela, Potomac Edison and West Penn have established at 14 different banks lines of credit ranging from $5 million to $30 million for short-term borrowings. Allegheny, Monongahela, Potomac Edison and West Penn have agreed to pay for each of the lines of credit above an annual cash fee no greater than 10 basis points on all or the balance of the line of credit.

Allegheny, Monongahela, Potomac Edison, and West Penn each propose to borrow short-term funds through the issuance of notes to banks and dealers in commercial paper in aggregate amounts not to exceed the following amounts outstanding at any one time: Allegheny—$165 million; Monongahela—$100 million; Potomac Edison—$115 million; and West Penn—$170 million. Applicants propose that such notes and commercial paper will be issued from time-to-time prior to December 31, 1997, provided that no such notes or commercial paper shall mature after June 30, 1998.

Each note payable to a bank will be dated as of the date of the borrowing which it evidences, will mature not more than 270 days after the date of issuance or renewal thereof, will bear interest at a mutually agreed upon rate, provided that the effective rate for any 30-day period, on an annualized basis, will not exceed prime plus 2 percentage points and may or may not have prepayment privileges. It is estimated that the maximum aggregate amount of any short-term borrowings on behalf of Applicants (except AGC) at any one time outstanding, when taken together with any commercial paper then outstanding and funds borrowed by such affiliates under the Money Pool, will not be in excess of $550 million.

The commercial paper will be in the form of promissory notes and will be of varying maturities, with no maturity more than 270 days after the date of issue.

AGC requests the authority to issue, from December 31, 1995 to December 31, 1997, commercial paper in an amount up to $75 million. AGC's commercial paper is backed by a funding commitment of a $50 million Revolving Credit Agreement dated as of May 15, 1985, with a group of seven banks (the ''Revolving Credit Agreement''). AGC is seeking to continue its borrowing authority under the Revolving Credit Agreement through December 31, 1997 and is seeking permission to establish through December 31, 1997 a line of credit of up to $25 million, but only if necessary and if the Revolving Credit Agreement is not sufficient. The Revolving Credit Agreement provides for a credit facility pursuant to which promissory notes (''Notes'') may be issued in the maximum aggregate principal amount of $50 million. The Notes will have a maturity of no later than December 31, 1998. The Agreement provides that the lending banks may extend the maturity of the Notes for one year periods. In order to extend the maturity date of the Notes beyond December 31, 1998, however, AGC must seek further Commission authorization. Total AGC debt outstanding, including the Revolving Credit Agreement, this commercial paper issuance, and a $25 million line of credit, but not including the Debentures and Medium Term Notes authorized previously by the Commission under File Nos. 70–7246, and 70–7548, will not at any time exceed $75 million.

Monongahela, Potomac Edison, and West Penn, severally and not jointly, guarantee 27%, 28%, and 45%, respectively, of the amount due the banks from AGC pursuant to the Revolving Credit Agreement. Monongahela, Potomac Edison, and West Penn request authority to extend their guarantees through December 31, 1997.

Applicants hereby seek to continue the Allegheny Power System Money Pool from December 31, 1995 to December 31, 1997. Allegheny is a participant in the Money Pool only insofar as it has funds available for lending through the Money Pool. Allegheny may not borrow from the Money Pool. AGC will be allowed to borrow from, but not invest in, the Money Pool.

Northeast Utilities, et al. (70–8052)

Northeast Utilities (''Northeast''), 174 Brush Hill Avenue, West Springfield, Massachusetts 01090–0010, a registered holding company, and its wholly owned subsidiaries (''Subsidiaries''), Western Massachusetts Electric Company (''WMECO''), 174 Brush Hill Avenue, West Springfield, Massachusetts 01090–0010, Holyoke Water Power Company (''Holyoke''), 1 Canal Street, Holyoke, Massachusetts 01040, and The Connecticut Light & Power Company (''CL&P''), Northeast Nuclear Energy Company (''Nuclear''), The Rocky River Realty Company (''Rocky River'') (Northeast and all Subsidiaries being ''Borrowers'') and Northeast Utilities Service Company (''NUSCO''), each of 107 Selden Street, Berlin, Connecticut 06037 (all companies collectively, ''Declarants''), have filed a post-effective amendment to their declaration filed under sections 6(a), 7 and 12(b) of the Act and rules 45 and 53 thereunder.

By order of the Commission dated July 29, 1988 (HCAR No. 24686) (''1988 Order''), all of the Subsidiaries, including other Northeast subsidiaries, entered into a revolving credit agreement, dated as of August 25, 1988, which permitted each of the subsidiaries to borrow up to $50 million, but not more than $50 million in the aggregate, on a short-term revolving credit basis through August 24, 1993. In addition, by order of the Commission dated August 18, 1989 (HCAR No. 24943) (''1989 Order''), Northeast, WMECO and CL&P entered into a revolving credit agreement, dated as of August 23, 1989, which permitted these subsidiaries to borrow up to $100 million, $105 million and $350 million, respectively, but not more than $350 million in the aggregate, on a short-term revolving credit basis through September 4, 1993.

By order dated November 23, 1992 (HCAR No. 25683) (''1992 Order''), Declarants were authorized, through December 31, 1995, to: (i) replace the two revolving credit facilities authorized by the 1988 Order and the 1989 Order with new revolving credit

facilities aggregating up to $360 million; (ii) issue notes (''Notes'') evidencing borrowing under such new revolving credit facilities; (iii) allow Northeast to guarantee the obligations of Nuclear and Rocky River under such new revolving credit facilities; and (iv) allow NUSCO to act as agent for such new revolving credit facilities.

Declarants now propose to: (i) extend through December 31, 2000 the existing revolving credit agreements pursuant to their terms; and (ii) amend the existing revolving agreements to, as described below—(a) change the margin rate applicable to the determination of the interest rate charged under the credit agreements, and (b) change the facility fees charged in connection with the credit agreements.

Pursuant to the 1992 Order, the interest rate under the Eurodollar interest option equals the Eurodollar Rate (as defined in the 1992 Order) plus a certain margin rate (''Margin''). The Margin for each Borrower varies, depending on the debt ratings provided by Moody's Investors Service Inc. and Standard and Poor's Corporation. Currently under the credit agreement, the Margin cannot exceed 0.625% for loans made at CL&P and WMECO and 0.75% for loans made to Northeast, Holyoke, Nuclear, and Rocky River. The Declarants request the flexibility to increase or decrease the Margins under the credit agreements from time to time during the term of the credit agreements, provided that the Margins will not exceed 1%.

The initial credit agreement facility fees under the 1992 Order equaled 0.2% per annum for the three-year credit agreement and 0.135% per annum for the 364-day credit agreements. The Declarants propose to increase either or both credit agreement facility fees by not more than 10 basis points during the term of the credit agreements if such an increase is needed to respond to changing market conditions.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

FR Doc. 95–24912 Filed 10–5–95; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36324; File No. SR–CSE–95–07]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by the Cincinnati Stock Exchange, Inc., Relating to the Preferencing of Public Agency Market and Marketable Limit Orders by Approved Dealers and Other Proprietary Members

September 29, 1995.

I. Introduction

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 22, 1995, the Cincinnati Stock Exchange, Inc. (''CSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change, and on September 28, 1995, Amendment No. 1 thereto,[3] as described in Items II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

II. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CSE hereby proposes to extend the CSE's pilot program regarding preferencing until March 29, 1996. The pilot was initially approved by the Commission on February 7, 1991, and is currently extended until October 2, 1995.

III. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the rule filing is to extend the existing pilot program of the Exchange relating to the preferencing of public agency market and marketable limit orders by approved dealers and other proprietary members. The Commission originally approved the pilot on February 7, 1991.[4] The Commission has subsequently extended the pilot several times.[5] The Exchange now seeks an extension of the program until March 29, 1996.

2. Statutory Basis

The exchange believes that the proposed rule change is consistent with Section 6(b) of the Act in general and furthers the objectives of Section 6(b)(5) in particular in that it will promote just and equitable principles of trade and remove impediments to and perfect the mechanisms of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The CSE does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The CSE informed the other Intermarket Trading System (''ITS'') participants of its intention to file this proposal to extend the preferencing pilot through March 29, 1996. The CSE previously solicited comments from other participants on its request for permanent approval.[6] The proposed extension would continue the program under the same terms and conditions as the existing pilot that was previously commented upon.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4 (1994).

[3] *See* letter from Robert Ackerman, Vice President, CSE, to Sharon Lawson, Senior Special Counsel, SEC, dated September 28, 1995. Amendment No. 1 amended the request for an extension through June 28, 1996, to an extension through March 29, 1996.

[4] *See* Securities Exchange Act Release No. 28866 (February 7, 1991), 56 FR 5854 (February 13, 1991).

[5] *See* Securities Exchange Act Release Nos. 29524 (August 5, 1991), 56 FR 38160 (August 5, 1991); 30353 (February 7, 1992), 57 FR 5918 (February 18, 1992); 31011 (Aug. 7, 1992), 57 FR 38704 (August 26, 1992); 32280 (May 7, 1993), 58 FR 28422 (May 13, 1993); 33975 (April 28, 1994), 59 FR 23243 (May 5, 1994); 34493 (August 5, 1994), 59 FR 41531 (August 12, 1994); 35717 (May 15, 1995), 60 FR 26909 (May 19, 1995).

[6] *See infra* note 14.

should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. § 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the CSE. All submissions should refer to File No. SR–CSE–95–07 and should be submitted by [insert date 21 days from date of publication].

V. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

A. Description

The CSE is an electronic exchange that uses multiple competing dealers rather than a single specialist. CSE members transmit orders, make markets, and receive executions and reports through remote terminals or computer interfaces from around the country. The preferencing program permits CSE dealers to retain and execute their internal order flow at the prevailing ITS best bid or offer (''ITS/BBO''), provided that there are no public agency limit orders on the CSE's National Securities Trading System (''NSTS'') limit order book at that price or better. To this end, the preferencing program permits CSE dealers to internalize order flow by eliminating price and time priority between CSE dealers, thereby enabling preferencing dealers to interact with public market and marketable limit orders they represent as agent

Specifically, the preferencing program gives preferencing dealers priority over same-priced (or superior-priced) professional agency or principal orders entered prior in time when interacting with a public order it represents as agent.[7] The dealer may interact with such orders either by (1) taking the contra-side position on the trade as principal (''paired order trade''), or (2) crossing the order with another customer order it represents as agent (''agency cross'').[8]

By way of example, if dealer A on the CSE is quoting at the ITS/BBO, dealer B can still internalize its order flow (even if he is not quoting at the ITS/BBO so long as dealer B executes the order at the ITS/BBO (or better) and there is no contra-side public agency order in NSTS at that price. If there is a public agency limit order in NSTS with priority, however, NSTS will automatically break the cross and match the incoming public agency order with the public limit order on the CSE book. The system rejects the CSE dealer's principal side of the attempted cross or, in the case of an attempted public agency cross, rejects the agency order required to yield priority to the order that was on the NSTS book.

In approving the initial preferencing program pilot, and subsequent extensions and expansions, the Commission imposed certain limitations and requirements on its operation. These conditions limit the number of issues in which a preferencing dealer may be registered to 350; require the Exchange to provide certain information to the Commission; prohibit preferenced trading for index arbitrage purposes when certain ''circuit breakers'' are in effect;[9] and prohibit a dealer from making cash payments for order flow that it preferences to itself.

The CSE proposes to extend the preferencing program pilot through March 29, 1996.

B. Discussion

After considering carefully the data and comments received on the CSE's preferencing program, the Commission finds that the CSE's proposal to extend its preferencing pilot program to March 29, 1996, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange. Specifically, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[10] which requires that the rules of an exchange be designed to promote just and equitable principles of trade, prevent fraudulent and manipulative acts, remove impediments to and perfect the mechanism of a free and open market and a national market system (''NMS''), and in general, to protect investors and the public interest.

In its August 1994 order extending the preferencing program,[11] the commission expressed concerns regarding what impact preferencing might have on the quality of the CSE market and the national market system. The Commission enumerated six reporting requirements to be submitted quarterly in order to facilitate evaluation of the CSE's preferencing program. In addition, the Commission required the CSE to submit an analysis detailing how the preferencing program has affected the quality of the CSE's market, including its effect on quote competition, market transparency, depth and liquidity, and improved quotations.[12] Specifically, the Commission instructed the CSE to analyze the effects of the preferencing program on the quality of market making by CSE preferencing dealers, and demonstrate that the preferencing program has resulted in added depth and liquidity to its market and improved quotations. The CSE subsequently filed interim reports with the Commission and submitted its pilot analysis.[13]

The data provided by the CSE attempts to prove that the Exchange's preferencing dealers add to the national market system because, among other things, (1) the average spread of CSE quotes in issues that have only preferencing dealers is ¼ point, which is narrower than any other regional exchange for these securities; (2) preferencing dealers are responsible for generating 4% of all quotes that establish a new ITS/BBO, more than twice the percentage of CSE's market share in NYSE-listed stocks; (3) preferencing dealers account for 46% of all ITS inbound orders in those issues that have both preferencing dealers and non-preferencing dealers; and (4) preferencing dealers execute approximately 62% of their orders between the ITS/BBO when the spread is greater the ⅛ point.

The Commission received several comment letters on the CSE proposal to adopt permanently the preferencing

[7] *See* CSE Rule 11.9(u).

[8] The majority of agency crosses are the result of a limit order resident in the dealer's proprietary system at the ITS/BBO, which is matched with an incoming contra-side market order. For example, it the market is 20 bid—20⅛ asked, and a dealer has a limit order to buy at 20, an incoming market sell order will be matched with that limit order because the dealer may not trade for its own account ahead of its own customer limit order. *See* CSE Rule 12.6(b).

[9] Specifically, the index arbitrage restriction permits preferencing dealers to preference their customer order flow that is related to index arbitrage only on plus or zero plus ticks when the Dow Jones Industrial Average (''DJIA'') declines by fifty points or more from the previous day's closing value. *See* Securities Exchange Act Release No. 28866, *supra* note 4.

[10] 15 U.S.C. § 78f(b)(5) (1988).

[11] *See* Securities Exchange Act Release No. 34493, *supra* note 5.

[12] *See id.*

[13] *See* letters from David Colker, Executive Vice President and Chief Operating Officer, CSE, to Arthur Levitt, Chairman, SEC, dated January 18, 1995 (''January Report''), and to Jonathan Katz, SEC, dated June 14, 1995 (''June Report'') (available to the public in File No. SR–CSE–95–03).

pilot, many of which challenged the CSE's statistics.[14] Some of the commenters proffered statistics to support their contention that the CSE merely serves as a means for firms to internalize order flow. Among other things, commenters alleged that (1) over 94% of preferencing dealers' executions are paired order trades; (2) only 4.8% of CSE trades can be characterized as trades between CSE dealers; and (3) CSE quotes are inaccessible to other ITS participants.

The Commission has examined the data provided by the CSE and commenters and believes it would be useful to analyze additional data before making a definitive determination on the pilot. To allow further evaluation of the market structure implications of permanently approving the CSE's preferencing program, the Commission requests that the CSE continue to submit the quarterly reports described in the Commission's previous orders approving extensions of the pilot. The Commission also will collect relevant data on its own to evaluate the pilot.

More importantly, the Commission is interested in exploring whether broader market structure initiatives can address the commenters' concerns regarding order interaction and the effects of preferencing on the NMS in general, and on order execution quality in particular. In this regard, the Commission recently proposed rules that attempt to address, among other things, the order interaction and best execution issues presented by preferencing of order flow.[15] Extension of the CSE pilot will allow the Commission an opportunity to study the implications of the proposals for the CSE's preferencing pilot during the pendency of the rulemaking process.

The Commission finds good cause for approving the proposed rule change, as amended, prior to the thirtieth day after the date of publication of notice of filing thereof in the Federal Register. The Commission believes that accelerated approval of the proposal is appropriate in order to avoid an interruption to the existing pilot while the Commission continues to collect data and consider broader market structure rules to address internalization.

[14] The Commission received negative comment letters from, among others, the New York Stock Exchange, American Stock Exchange, and Boston Stock Exchange. These and other correspondence received regarding the CSE's request for permanent approval of the pilot program are available to the public in File No. SR–CSE–95–03.

[15] *See* Securities Exchange Act Release No. 36310 (September 29, 1995).

VI. Conclusion

It Is Therefore Ordered, pursuant to Section 19(b)(2)[16] that the proposed rule change, as amended, is hereby approved on an accelerated basis, and the preferencing pilot is extended through March 29, 1996.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 95–24908 Filed 10–5–95; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36311; File No. SR–NASD–95–34]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Granting Temporary Approval of Proposed Rule Change to Extend Certain SOES Rules Through January 31, 1996

I. Introduction

On August 11, 1995, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder.[2] The NASD proposes to extend through January 31, 1996 certain changes to its Small Order Execution System (''SOES'') that were originally implemented in January 1994 for a one-year pilot period (''January 1994 Amended SOES Rules'').[3] These rules subsequently were modified in January 1995 (''January 1995 Amended SOES Rules'')[4] and further modified in March 1995 (''March 1995 Amended SOES Rules'').[5] The March 1995 Amended SOES Rules are scheduled to expire on October 2, 1995, and the NASD seeks to extend these until January 31, 1996. Without further Commission action, the SOES rules would revert to those in effect prior to January 1994.

Notice of the proposed rule change appeared in the Federal Register on August 31, 1995.[6] Eleven comments were received in response to the Commission release. For the reasons discussed below, this order approves the proposed rule change until January 31, 1996.

II. Description of the Current and Prior Proposals

The NASD proposes to extend until January 31, 1996 the March 1995 Amended SOES Rules. Specifically, the NASD proposes to extend until January 31, 1996 changes that:

(1) Reduce the minimum exposure limit for ''unpreferenced'' SOES orders from five times the maximum order size to two times the maximum order size, and eliminate the exposure limits for ''preferenced'' SOES orders; and

(2) Maintain the availability of an automated function for updating market maker quotations when the market maker's exposure limit has been exhausted (market makers using this update function may establish an exposure limit equal to the maximum order size for that security).

III. Comments

The current proposal attracted eleven comments, eight supporting the proposal and three opposing it. The comments raised issues similar to those raised in connection with previous amendments to the SOES Rules.

Generally, commenters supporting the proposals have argued that the various amendments to the SOES Rules have been necessary to limit the exposure of market makers to multiple SOES executions, which benefits retail investors by producing narrower spreads and more liquid markets. Some commenters supporting the proposal also argued for additional limits on market makers' SOES exposure, such as a reduction in the SOES maximum order size to 500 shares.

Commenters opposed to the proposals have argued that the statistical and market quality data cited by the NASD[7] in support of the various amendments to the SOES Rules are not sufficient to

[16] 15 U.S.C. § 78s(b)(2) (1988).

[1] 15 U.S.C. § 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4 (1994).

[3] Securities Exchange Act Release No. 33377 (Dec. 23, 1993), 58 FR 69419 (Dec. 30, 1993) (approving the Interim SOES Rules on a one-year pilot basis effective January 7, 1994). *See also* Securities Exchange Act Release No. 33424 (Jan. 5, 1994) (order denying stay and granting interim stay through January 25, 1994) and Securities Exchange Act Release No. 33635 (Feb. 17, 1994) (order denying renewed application for stay).

[4] Securities Exchange Act Release No. 35275 (Jan. 25, 1995), 60 FR 6327 (Feb. 1, 1995).

[5] Securities Exchange Act Release No. 35535 (Mar. 27, 1995), 60 FR 16690 (Mar. 31, 1995).

The March 1995 Amended SOES Rules did not include the two features found in the January 1994 Amended SOES Rules that:

(1) Reduced the maximum size order eligible for SOES execution from 1,000 shares to 500 shares; and

(2) Prohibited short sale transactions through SOES.

The January 1995 Amended SOES Rules continued all of the January 1994 Amended SOES Rules, except for the short sale prohibition and, as noted, the March 1995 Amended SOES Rules continued only the first two January 1994 Amended SOES Rules.

[6] Securities Exchange Act Release No. 36154 (Aug. 25, 1995), 60 FR 45502 (Aug. 31, 1995).

[7] *See infra* notes 16–20 and accompanying text.

support the NASD's position. They contend that the studies on which the NASD relies fail to demonstrate any increase in market quality as a result of the various amendments to the rules and that market makers have ample opportunity to update their quotes in order to avoid multiple SOES executions.

IV. Discussion

The Commission must approve a proposed NASD rule change if it finds that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder that govern the NASD.[8] In evaluating a given proposal, the Commission examines the record before it and relevant factors and information.[9] The Commission believes that approval of the proposal through January 31, 1996 meet the above standards. Specifically, the Commission believes that the current minimum exposure limit and automated quotation update feature are appropriate while the NASD considers other methods for handling small orders from retail customers.[10]

The Commission believes that a sufficient basis exists for approving the NASD's proposal to continue the current operation of SOES. The system provided and continues to provide retail investors enhanced opportunity to obtain execution of orders in size up to 1,000 shares and, accordingly, has improved access to the Nasdaq market.

In addition, the March 1995 Amended SOES Rules resulted in an increase in the SOES minimum exposure limit from 1,000 shares to 2,000 shares. Moreover, the March 1995 Amended SOES Rules continued the methodology for calculating a market maker's outstanding exposure limit that excluded orders executed pursuant to a preferencing arrangement. Under the SOES Rules prior to the January 1994 Amended SOES Rules, both preferenced and unpreferenced orders were considered when calculating a market maker's remaining exposure limit. Thus, in relative terms, the 2,000 share exposure limit potentially provides greater liquidity under certain conditions compared to the pre-January 1994 Amended SOES Rules' 5,000 share minimum exposure limit.

The Commission continues to believe that the current operation of SOES has eliminated the economically significant restrictions imposed on order entry firms by the January 1994 Amended SOES Rules. The Commission believes that while the proposal does not restore the pre-January 1994 Amended SOES Rules minimum exposure limit, it provides customers fair access to the Nasdaq market and reasonable assurance of timely executions. In this regard, the maximum order size equals the size requirement prescribed under the Firm Quote Rule and NASD rules governing the character of market maker quotations.[11] Moreover, market maker's minimum exposure limit for unpreferenced orders is double its minimum size requirement prescribed under these rules.[12]

The Commission also believes that extending the automated update function is consistent with the Firm Quote Rule.[13] The update function provides market makers the opportunity to update their quotations automatically after executions through SOES;[14] under the Commission's Firm Quote Rule, market makers are entitled to update their quotations following an execution and prior to accepting a second order at their published quotes.[15]

In connection with its proposal, the NASD submitted data it believes supports extending the current minimum exposure limit and the automated quotation update feature.[16] In addition, in connection with the Commission's consideration of the NASD's proposal, the Commission requested that the NASD provide any industry-wide or firm-specific data that market maker firms have provided the NASD concerning the effect SOES has had on profitability or the market making function.[17] According to the NASD, since the restoration in March 1995 of the maximum order size of 1,000 shares, the volume of trading through SOES has increased both in absolute terms and relative to overall Nasdaq volume. As a result, the NASD believes, some market makers have withdrawn from making a market in certain Nasdaq securities. The NASD argues that failure to extend the March 1995 Amended SOES Rules would exacerbate this withdrawal.

The Commission is not convinced, however, that the data submitted by the NASD demonstrates a casual relationship between the change in the operation of SOES as a result of the March 1995 Interim SOES Rules and the decline in the number of market makers in the selected securities. Rather, the Commission believes the NASD's data demonstrates, at best, a correlation between the two. The NASD did not control for other factors that may have affected the number of market makers in the securities covered by their study (*e.g.*, decreased spreads; increased volatility; seasonality; and increased capital requirements associated with increased prices). Such factors could potentially explain the decline in the number of market makers independent of SOES activity. In addition, the NASD

[8] 25 U.S.C. 78s(b). The Commission's statutory role is limited to evaluating the rules as proposed against the statutory standards. *See* S. Rep. No. 75, 94th Cong., 1st. Sess., at 13 (1975).

[9] In the Securities Acts Amendments of 1975, Congress directed the Commission to use its authority under the Act, including its authority to approve SRO rule changes, to foster the establishment of a national market system and promote the goals of economically efficient securities transactions, fair competition, and best execution. Congress granted the Commission ''broad, discretionary powers'' and ''maximum flexibility'' to develop a national market system and to carry out these objectives. Furthermore, Congress gave the Commission ''the power to classify markets, firms, and securities in any manner it deems necessary or appropriate in the public interest or for the protection of investors and to facilitate the development of subsystems within the national market system.'' S. Rep. No. 75, 94th Cong., 1st. Sess., at 7 (1975).

[10] *See* letter from Joan C. Conley, Secretary, NASD, to Mark Barracca, Branch Chief, Division of Market Regulation, SEC (Sept. 22, 1995) (submission of File No. SR–NASD–95–42, the NASD's NAqcess proposal which is designed to replace SOES).

[11] *NASD Manual*, Schedules to the By-Laws, Schedule D, Part V, Sec. 2(a), (CCH) ¶ 1819.

[12] 17 CFR 240.11Ac1–1(c). Nonetheless, the Commission is concerned about the potential for delayed and/or inferior executions. In this regard, the Commission expects the NASD to monitor the extent to which exposure limits are exhausted, the extent to which the automated quotation update feature is used, and the effects these two aspects have on liquidity. Moreover, the Commission expects the NASD to consider the possibility of enhancements to eliminate the potential for delayed and/or inferior executions. The Commission expects the NASD to report back to the Commission on these issues by December 1, 1995.

[13] The SOES automated update function is also consistent with the NASD's autoquote policy which generally prohibits autoquote systems, but allows automatic updating of quotations ''when the update is in response to an execution in the security by the firm.'' *NASD Manual*, Schedules to the By-Laws, Schedule D, Part V, Sec. 2 (CCH ¶ 1819).

[14] The NASD has indicated that 21 percent of market makers in Nasdaq National Market securities use the automated quotation update feature for 38 percent of all market making positions in Nasdaq National Market securities. Letter from Richard Ketchum, Executive Vice President and Chief Operating Officer, NASD, to Jonathan G. Katz, Secretary, SEC (Mar. 22, 1995).

[15] The Firm Quote Rule requires market makers to execute orders at prices at least as favorable as their quoted prices. The Rule also allows market makers a reasonable period of time to update their quotations following an execution, allows market makers to reject an order if they have communicated a quotation update to their exchange or association, and provides for a size limitation on liability at given quote. 17 CFR 240.11Ac1–1(c)(2). *See also*, Securities Exchange Act Release No. 14415 (Jan. 26, 1978), 43 FR 4342 (Feb. 1, 1978).

[16] Letter from Richard G. Ketchum, Executive Vice President and Chief Operating Officer, NASD, to Brandon Becker, Director, Division of Market Regulation, SEC (Aug. 1, 1995).

[17] Letter to Richard G. Ketchum, Executive Vice President and Chief Operating Officer, NASD, from Brandon Becker, Director, Division of Market Regulation, SEC (Aug. 25, 1995). As of the issuance of this order, the NASD has not provided any data in response to this request.

selected securities with the largest decline in the number of market makers. From an economic and statistical basis, this introduces severe statistical problems and a bias toward those securities with the largest number of market makers. This selection, under any circumstance, would find the largest absolute changes in the number of market makers.

In further support of its proposal, the NASD continues to rely on studies previously submitted to the Commission in support of the amendments to SOES.[18] In its order approving both the January 1995 and March 1995 Amended SOES Rules, however, the Commission expressed its belief that this data submitted by the NASD demonstrated neither significant improvement to nor serious deterioration in the quality of the Nasdaq market subsequent to the adoption of the January 1994 Amended SOES Rules.[19] The information submitted since does not alter the Commission's original assessment. The Commission, therefore, continues to believe that the data submitted by the NASD demonstrates neither a significant improvement to nor serious deterioration in the quality of the Nasdaq market subsequent to the adoption of the January 1994 Amended SOES Rules.[20] Moreover, the Commission believes this is true whether the amended SOES rules are viewed collectively or individually. Thus, the Commission's evaluation of the data submitted by the NASD does not change its determination to approve the proposal to extend the March 1995 Amended SOES Rules through January 31, 1996.

V. Conclusion

As indicated above, the Commission has determined to approve the October 1995 Amended SOES Rules through January 31, 1996. In light of the balance of factors described above and the limited duration of the current proposal, the Commission believes extension of the reduction in the minimum exposure limit, the limitation of the exposure limit to unpreferenced orders, and the addition of an automatic quotation update feature is consistent with the Act.

The Commission, in the exercise of the authority delegated to it by Congress, and in light of its experience regulating securities markets and market participants, has determined that approval of these temporary changes to the SOES Rules until January 31, 1996 is consistent with maintaining investor protection and fair and orderly markets, and that these goals, on balance, outweigh possible anti-competitive effects on order entry firms and their customers.

Accordingly, the Commission finds that the rule change is consistent with the Act and the rules and regulations thereunder applicable to the NASD and, in particular, Sections 15A(b)(6), 15A(b)(9), and 15A(b)(11). In addition, the Commission finds that the rule change is consistent with the Congressional objectives for the equity markets, set out in Section 11A, of achieving more efficient and effective market operations, fair competition among brokers and dealers, and the economically efficient execution of investor orders in the best market.

It is Therefore Ordered, pursuant to Section 19(b)(2) of the Act, that the instant rule change SR–NASD–95–34 be, and hereby is, approved, effective October 3, 1995 through January 31, 1996.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 95–24909 Filed 10–5–95; 8:45 am]

BILLING CODE 8010–01–M

[18] Securities Exchange Act Release No. 35080 (Dec. 9, 1994), 59 FR 65109 (Dec. 16, 1994) and letter from John F. Olson, Counsel for the NASD, Gibson, Dunn & Crutcher, to Jonathan Katz, Secretary, SEC (Dec. 30, 1994) (submitting in connection with File No. SR–NASD–94–68 analysis entitled *The Association Between the Interim SOES Rules and Nasdaq Market Quality* prepared by Dean Furbush, Ph.D., Economists Incorporated (Dec. 30, 1994)).

[19] Securities Exchange Act Release No. 35275 (Jan. 25, 1995), 60 FR 6327 (Feb. 1, 1995).

[20] Nonetheless, the Commission continues to be interested in data and studies demonstrating the effect, if any, of the SOES rule changes on the Nasdaq market.

[Release No. 34–36323; File No. SR–BSE–95–14]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by the Boston Stock Exchange, Inc., Relating to its Competing Specialist Pilot Program

September 29, 1995.

I. Introduction

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 25, 1995, the Boston Stock Exchange, Inc. (''BSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change, and on September 27, 1995, Amendment No. 1 thereto,[3] as described in Items II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

II. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The BSE seeks to extend the current pilot program for competing specialists on its floor until March 29, 1996, and to adopt clarifying language for limit order execution under the pilot. The Exchange also proposes to expand the program to four competing specialists that may trade up to 100 stocks each.

III. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to extend the current pilot program for competing specialists until March 29, 1996 and to clarify the priority rule regarding the execution of limit orders on the central limit book.[4]

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4 (1994).

[3] See letter from Karen Aluise, Assistant Vice President, BSE, to Glen Barrentine, Senior Counsel, SEC, dated September 27, 1995. Amendment No. 1 amended the request for an extension through June 28, 1996, to an extension through March 29, 1996.

[4] The language of the proposed rule change is as follows, with additions to the current rule in italics and deletions in brackets:

Because there is only one Exchange market in a security subject to competition, all limit [Limit] orders *sent to the Exchange will be maintained by the BEACON System's central limit book and will be* [entrusted to each competing specialist are to be represented and] executed strictly according to time priority as to receipt of the order in the BEACON System, *irrespective of firm order routing procedures.*

This rule change previously was published for public comment in Securities Exchange Act Release No. 36100 (August 14, 1995), 60 FR 43628 (August 22, 1995), as an amendment to a BSE request for permanent approval of the competing specialist program. See File No. SR–BSE–95–02.

This competing specialist program has been operating on a pilot basis since May 18, 1994.[5] In addition to extending the pilot until March 29, 1996, the Exchange proposes to expand the pilot. The program currently provides for up to two competing specialists in a stock on the floor of the Exchange in addition to the regular specialists. The Exchange is seeking to increase the number of competitors from two to four. The Exchange also proposes to increase the number of stocks per competing specialist firm from 20 to 100 for the duration of the pilot program.

The Exchange believes that these increases are reasonable and will enable the Exchange to further evaluate the effectiveness of the program on a wider scale to determine if any changes are necessary to improve the program and the Exchange's market-making function generally. The Exchange believes the program has proven to provide adequate protection of customer orders sent to the Exchange and has maintained a true agency auction market for customer orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)(5) of the Act in that it furthers the objectives to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest; and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received comments on the proposed rule change.[6]

[5] See Securities Exchange Act Release No. 34078 (May 18, 1994), 59 FR 27082 (May 25, 1994).

[6] The Commission received two comment letters regarding the BSE's request for permanent approval of the competing specialist program. See letter from Paula Gavin, Chair, NYSE Individual Investors Advisory Council, to Chairman Arthur Levitt, SEC, dated July 17, 1995 (''Gavin Letter'') (asserting that preferencing programs deny orders the benefits and protections of auction market trading); and letter from Robert Jennings, Faculty Fellow and Professor of Finance, Indiana University School of Business, to Jonathan Katz, Secretary, SEC, dated June 30, 1995 (containing a preliminary draft of an academic paper from Indiana University that studied the short term effects of preferencing on market quality and found any such effects to be minimal). These letters are available at the Commission in File No. SR–BSE–95–02.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street NW., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the BSE. All submissions should refer to File No. SR–BSE–95–14 and should be submitted by October 27, 1995.

V. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

A. Description

The BSE normally assigns one specialist to each stock traded on the Exchange floor (the ''regular'' specialist). The competing specialist program allows the Exchange to approve additional specialists for a particular stock (''Competing Specialists''), who compete with each other and the regular specialist on the trading floor of the Exchange.[7] The competing specialist pilot currently limits the number of specialists that can compete in a stock to three—one regular specialist and up to two Competing Specialists. The pilot also limits each Competing Specialist to a maximum of 10 stocks unless the Market Performance Committee approves an increase of up to 20 stocks per applicant firm. The BSE proposes to expand these limitations to allow up to four Competing Specialists that may compete in up to 100 stocks each.

Under the pilot program, Competing Specialists have the same affirmative and negative market making obligations as regular specialists.[8] The regular specialist, however, remains responsible for (1) updating all quotations,[9] (2) coordinating all openings and reopenings to ensure that they are unitary, (3) inputing quotations on the Intermarket Trading System (''ITS'') to reflect the best BSE quote among all the specialists,[10] and (4) coordinating trading halts.

Under the competing specialist program, the Exchange's rules governing the auction market principles of priority, parity, and precedence remain unchanged for quotes at the ITS/BBO.[11] Specialists quoting at the ITS/BBO have priority over specialists not quoting at the ITS/BBO. Under the rules, if two or more specialists are quoting at the ITS/BBO, the earliest bid/offer at that price has time priority and will be filled first up to its specified size. If the specialists are on both price and time parity at the ITS/BBO, all bids/offers equal to or greater than the size of the contra-side order are on parity and entitled to precedence over smaller orders.

When none of the specialists are quoting at the ITS/BBO, the competing specialist program permits orders to be directed to a particular specialist for execution (*i.e.*, there is no priority between quotes outside of the ITS/BBO).[12] If a particular specialist is not

[7] The Commission notes that the Competing Specialists must conduct their activity on the floor of the Exchange. There are no existing Exchange rules that allow specialists to operate off the floor of the Exchange. Such a change in operations would require Commission approval.

[8] Among the obligations imposed upon specialists by the Exchange, and by the Act and rules thereunder, is the maintenance of fair and orderly markets. See, *e.g.*, 17 CFR 240.11b–1; BSE Rules, Ch. XV, Section 2.

[9] The BSE needs to implement system upgrades that will allow the Competing Specialists to enter their own quotes into BEACON. The system will coordinate the aggregation and dissemination of quotations, but the regular specialist will continue to coordinate openings, reopenings, and trading halts. See *infra* text accompanying note 28.

[10] See *id*. Regardless of the number of specialists competing in a stock, the BSE displays only one consolidated quotation (the best quote among all the specialists) to other markets in the National Market System at all times.

[11] See BSE Rules, Ch. II. Section 6.

[12] For example, assume that the ITS/BBO is 20 bid to 20⅛ offered, and specialist A is bidding 19¾ while specialist B is bidding 19½. A market order to sell may be directed to specialist B for execution even through specialist A has a better bid because neither specialist is bidding at the ITS/BBO. Under the competing specialist program, specialist B would execute the order at 20 (the ITS best bid) or better. If specialist A had been bidding 20 (the ITS best bid), specialist A would have had priority to execute the order even though it was directed to specialist B.

specified, the order is directed to the regular specialist unless the routing firm is affiliated with a Competing Specialist.[13] In that case, the order is routed automatically to that member firm's affiliated specialist, thereby preventing member firms affiliated with a specialist from routing non-profitable orders through the BSE's automated order routing system (''BEACON'') to another specialist when market conditions are unfavorable.

All limit orders in BEACON are represented and executed strictly according to time priority, irrespective of firm routing procedures.[14] BEACON (which handles approximately 95% of all order flow on the BSE) automatically executes incoming orders against any contra-side orders on the limit order book. Prior to automatic execution, however, all market and marketable limit orders are exposed to the designated specialist for 15 seconds for possible price improvement.[15] Only where there is no contra-side order on the limit order book (and no other specialist has a priority quote at the ITS/BBO) is the incoming order routed to the designated specialist for execution.

The BSE represents that it is in the process of developing additional enhancements to BEACON to assist the efficiency of the competing specialist program. First, at the outset of the pilot only the regular specialist was sent quote alerts [16] and trade alerts [17] in a given security. The BSE represents that BEACON has been modified so that such alerts are currently sent to the Competing Specialist.[18] Additionally, BEACON recently was enhanced to alert the regular specialist to trade-throughs of the BSE market.[19] The Exchange anticipates providing this alert to Competing Specialists as well.[20] In addition, the regular specialist currently must coordinate pre-openings with Competing Specialist verbally. The BSE expects to implement shortly improvements to BEACON that enable each specialist to directly enter pre-opening trading interest into BEACON.[21]

In addition, Competing Specialists currently do not have the capability to enter their own quotes into BEACON, but rather must communicate them orally to the regular specialist who then enters the quote into BEACON on the Competing Specialist's behalf. In order to encourage competitive quoting by all specialists making markets in a security, the BSE has been working to modify BEACON so that the system will accept quotes from Competing Specialists. Because there currently is only one quote entered into the system by the regular specialist, BEACON presently routes orders as directed without systematically determining whether another specialist may have a priority quote at the ITS/BBO. Once the system is enhanced so that BEACON accepts quotes from each specialist directly, the BSE will also reprogram BEACON to route incoming orders to the specialist with priority on the Exchange at the ITS/BBO, or, if no such priority has been established, to the designated specialist.[22]

B. Discussion

The Commission finds that the BSE's proposal to extend its competing specialist pilot program, as amended, to March 29, 1996, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange. Specifically, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[23] which requires that the rules of an exchange be designed to promote just and equitable principles of trade, prevent fraudulent and manipulative acts, remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

In its original pilot approval order, the Commission expressed concerns regarding what impact the competing specialist program might have on the BSE market. To this end, the Commission requested that the BSE submit quarterly data reports and a report analyzing such data.[24] The BSE has filed these interim reports with the Commission.[25]

The data submitted by the BSE indicates that the volume of orders directed to the BSE in the stocks with multiple specialists increased steadily during the pilot. In addition, the depth of the limit order book for the stocks increased, indicating that firms are sending both market and limit orders to their affiliated specialists.

Finally, while the BSE has provided evidence that the competing specialist program has increased order flow to the Exchange, the data regarding quote competition between specialists in a particular security is mixed. The data shows an increase in the volume of the BSE's incoming ITS commitments for the securities traded pursuant to the competing specialist program. The data also indicates, however, that there is a lack of interaction by the regular specialist with incoming orders directed to a competing specialist. Specifically, directed orders are almost always executed by the designated specialist. Under the program's rules, if the specialists were quoting at the ITS/BBO, they would at times have priority over the designated specialist and intercept some of the directed order flow. While this data is inconclusive, the Commission believes that certain system enhancements may facilitate quote competition on the BSE.[26]

In addition, an extension of the pilot will enable the BSE to provide additional data for a more thorough analysis of the effects of multiple specialists on the BSE market and the national market system. Accordingly, during the extension of the pilot, the Commission requests that the BSE continue to submit the quarterly reports described in the pilot approval order.[27] The Commission also requests that the BSE include in future reports data identifying the percentage of BSE quotes that either match or better the ITS/BBO. This data should isolate stocks in which there are multiple specialists and be compared to statistics for stocks with only one specialist.[28]

[13] As noted above, however, if the Competing Specialist is quoting the ITS/BBO and clearly has established priority on the BSE floor, then the Competing Specialist will fill the order despite the default routing to the regular specialist.

[14] The BSE is proposing to codify this policy in Chapter XV, Section 18, of the BSE Rules.

[15] See BSE Rules, Ch. II, § 6.

[16] Quote alerts are messages sent by BEACON to a BSE specialist when a quote from among the ITS participants occurs at or through the price at which there is a limit order on the BSE book.

[17] Trade alerts are messages sent by BEACON to the BSE specialist when a trade occurs among the ITS participants at the price of an outstanding limit order on the specialist's book.

[18] Conversation between George Mann, General Counsel and Senior Vice President, BSE, and N. Amy Bilbija, Attorney, Commission, on June 23, 1995.

[19] A ''trade-through'' of the BSE market occurs whenever another ITS Participant initiates the purchase of a security at a price that is higher than the price at which the security is being offered (or initiates the sale at a price lower than the price at which the security is being bid) at the time of purchase (or sale) on the BSE.

[20] See BSE January Report, *infra* note 25.

[21] See id.

[22] See *infra* note 38.

[23] 15 U.S.C. 78f(b)(5) (1988).

[24] See Securities Exchange Act Release No. 34078, *supra* note 5.

[25] See Competing Specialist Initiative January 1995 Report, submitted to the Commission on February 13, 1995 (''BSE January Report''); and letter from Karen Aluise, Assistant Vice President, BSE, to N. Amy Bilbija, Attorney, SEC, dated April 28, 1995 (''BSE April Report''). These reports are available in the public file for SR–BSE–95–02.

[26] See *infra* note 28.

[27] See Securities Exchange Act Release No. 34078, *supra* note 5.

[28] As discussed above, see *supra* text accompanying note 9, the BSE needs to adopt enhancements to BEACON to permit Competing

More importantly, the Commission is interested in exploring whether broader market structure initiatives can address the commenters' concerns regarding order interaction and the effects of referencing on the NMS in general, and on order execution quality in particular. In this regard, the Commission recently proposed rules that attempt to address, among other things, the order interaction and best execution issues presented by referencing of order flow.[29] Extension of the BSE pilot will allow the Commission an opportunity to study the implications of these proposals for the BSE's competing specialist pilot.

The Commission finds good cause for approving the proposed rule change, as amended, prior to the thirtieth day after the date of publication of notice of filing thereof in the Federal Register. The Commission believes that accelerated approval of the proposal to extend the pilot is appropriate in order to avoid an unnecessary interruption to the pilot while the Commission conducts its market structure rulemaking and continues to collect data. Moreover, the Commission received only minimal comment on the BSE proposal to adopt the pilot on a permanent basis, making it unlikely that additional comment would be submitted regarding the extension. The Commission also believes that accelerated approval of the clarifying language to the limit or order execution rule is appropriate. The rule, which merely clarifies the existing practice, was previously published for public comment for the full statutory period [30] and no comments were receive on the proposal.

Finally, the Commission believes that accelerated approval of the proposed expansion of the program to four Competing Specialists that may compete in up to 100 securities is appropriate. Expansion of the program will provide the Commission with additional data upon which to decide whether the program should be permanently approved. In addition, the Commission published the BSE's request for permanent approval, which contained no destructions on the number of specialist or the number of stocks in which they could compete, for the full statutory period.[31] Only one comment letter that criticized the proposal was received.[32] The Commission will consider that comment when deciding either to approve the BSE's request to make the competing specialist program. permanent.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2),[33] that the proposed rule change to extend the BSE's competing specialist program as amended, through March 29, 1996, is hereby approved on an accelerated basis.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 95–24910 Filed 10–5–95; 8:45 am]

BILLING CODE 8010–01–M

Specialists to enter their own quotes into the system and to enable orders to be automatically routed to the specialist with priority under the rules. During the pilot extension, the Commission expects the BSE to continue developing these system enhancements, and expects progress to be made toward implementation of direct quote entry capability and systematic routing of orders.

[29] See Securities Exchange Act Release No. 36310 (September 29, 1995).

[30] See *supra* note 4.

[31] See Securities Exchange Act Release No. 35404 (February 22, 1995), 60 FR 10882 (February 28, 1995).

[32] See Gavin Letter, *supra* note 6.

[33] 15 U.S.C. 78s(b)(2) (1988)

[Release No. 34–36321; File No. SR–NASD–95–36]

Self-Regulatory Organizations; Order Granting Accelerated Approval to Proposed Rule Change by National Association of Securities Dealers, Inc., Relating to Schedule B to the NASD By-Laws

September 29, 1995.

On August 22, 1995, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder.[2] The proposed rule change amends Schedule B to the NASD By-Laws [3] to delete informational text on the number of members of the NASD Board of Governors (''Board'') elected from each district.

Notice of the proposed rule change, together with the substance of the proposal, was provided by issuance of a Commission release (Securities Exchange Act Release No. 36153, August 25, 1995) and by publication in the Federal Register (60 FR 45506, August 31, 1995). No comment letters were received. This order grants accelerated approval to the proposed rule change.

Article VII, Section 4(b) of the By-Laws requires that each district shall elect one Board member, authorizes the Board to determine which districts, if any, shall elect more than one Governor, and—in general—authorizes the Board to make appropriate changes in the number or boundaries of the districts or the number of Governors elected by each district to provide fair representation of members and districts. Pursuant to Article VII, Section 4(b), a total of 15 current members have been elected by the districts.

Schedule B currently provides that two members shall be elected from two of the districts and three members shall be elected from one of the districts. The NASD has stated that inclusion of the text regarding district representation on the Board in Schedule B to the NASD By-Laws was intended to be informational only. The NASD also has stated that it believes that the informational language in Schedule B to the NASD By-Laws specifying the number of Governors from each district unnecessarily limits the ability of the Board to act under Section 4(b) to make changes in the composition of the Board.

The NASD's proposal also may assist the NASD in adopting certain recommendations recently made by the NASD Select Committee on Structure and Governance (''Select Committee''). The Select Committee recently issued a report (''Committee Report'') recommending changes in the NASD's existing governance structure.[4] The Committee Report recommended, among other things, that the NASD increase public representation on its governing bodies, reform its disciplinary procedures and act to regulate broker-dealers and their personnel separately from regulation of the over-the-counter market, including The Nasdaq Stock Market (''Nasdaq'').[5] The NASD Board has agreed in principle to increase its public representation as recommended in the Committee Report.

Therefore, the NASD proposed to amend Schedule B to the NASD By-Laws to delete provisions that specify the number of members of the Board currently approved to be elected from each district in order to ensure that the Board has flexibility to act with respect to the composition of the Board of Governors.

The Commission finds that the proposed rule change is consistent with the provisions of Section 15A(b)(4) of the Act.[6] Section 15A(b)(4) requires that

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] NASD Manual, Schedules to the By-Laws, Schedule B (CCH) ¶ 1772.

[4] NASD, Report of The NASD Select Committee on Structure and Governance to the NASD Board of Directors (September 19, 1995).

[5] See *id.* at C–21–22.

[6] 15 U.S.C. 78*o*–3.

NASD rules provide for the fair representation of its members in the selection of its directors and administration of its affairs, as well as for the inclusion of Board members who represent issuers and investors. The proposed rule change satisfies both the basic requirements of Section 15A(b)(4) and the provision's overall objective in seeking to ensure effective public representation on the governing boards of the NASD.[7] The proposed rule change also diminishes the ability of one segment of the NASD membership to dominate the NASD Board, thereby enhancing the ability of the NASD Board to act in the best interests of the public and the NASD membership as a whole.[8] The Commission, therefore, concludes that the proposed amendments to Schedule B are consistent with Section 15A(b)(4) of the Act.

The NASD has requested that the Commission approve the proposed rule change on or before September 30, 1995, which is prior to the 30th day following publication of notice of the filing of such Amendments in the Federal Register, in order that the new rule may be effective with respect to the NASD's election procedures which commence on October 1, 1995 with respect to Board membership in 1996.

Pursuant to section 19(b)(2) of the Act,[9] the Commission finds good cause for approving the proposed rule change, as amended, prior to the 30th day after publication in the Federal Register. The proposed rule change will permit the NASD to reduce the proportionate representation of industry-affiliated Governors on the NASD Board, thereby increasing the proportionate representation of public Governors on the NASD Board. The Commission also believes it is important to enhance the representation of other NASD constituencies on the NASD Board. Because the Commission believes that the proposed rule change will enhance the opportunities of various NASD constituencies to play a meaningful role in NASD affairs, the Commission believes that the rule filing should be approved without delay.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that SR–NASD–95–36 be, and hereby is, approved effective immediately.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30–3(a)(12).

Jonathan G. Katz,

Secretary.

[FR Doc. 95–24913 Filed 10–5–95; 8:45 am]

BILLING CODE 8010–01–M

[7] The Commission has previously addressed issues of proportional representation on the boards of directors of national securities exchanges. Section 6(b)(3) of the Act imposes the same requirements on national securities exchanges as Section 15A(b)(4) imposes on the NASD. The Commission disapproved a proposal by the Chicago Board Options Exchange (''CBOE'') (Securities Exchange Act Release No. 22058 (May 21, 1985), 50 FR 23090) which would have increased the minimum number of On-Floor Directors. The Commission noted that domination by the floor membership of the CBOE Board and a resulting decrease in the proportion of retail firm and public governors on the Board would have seriously weakened the ability of the Board to carry out the purposes of the Act and enforce compliance with Exchange and Commission rules, as required by Section 6(b)(1). In addition, the Commission stated that the numerical domination by one faction of the CBOE membership, in contravention of Section 6(b)(3) of the Act, might make it difficult for the Board to act in the best interests of the public or the CBOE as a whole and could impede efforts by the Board to vigorously enforce Commission or Exchange rules not favored by the floor membership. The Commission also viewed the proposal as being inconsistent with Section 6(b)(5) which requires the rules of an exchange to be designed to protect investors and their public interest.

[8] *Cf. id.*

[9] 15 U.S.C. 78s(b)(2).

[Release No. 34–36319; File No. SR–Phlx–95–72)

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc., Relating to Extending the Circuit Breaker Pilot Program

September 29, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on September 18, 1995, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx proposes to extend the effectiveness of its circuit breaker pilot program, which appears in Phlx Rule 133, until October 31, 1996. Generally, Rule 133 provides for a one hour trading halt if the Dow Jones Industrial Average (''DJIA'') declines 250 or more points from its previous day's closing level, and, thereafter, a two hour trading halt if the DJIA declines 400 points from the previous day's closing level.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of this proposal is to extend the Exchange's circuit breaker pilot program for a one-year period, in order to afford the Exchange and the Commission additional time to evaluate the effectiveness of the pilot program. The Exchange's circuit breaker rule provides an important safety mechanism in conjunction with the circuit breaker rules of other self-regulatory organizations (''SROs''). The Commission approved the Exchange's circuit breaker proposal on a temporary basis in 1988.[2] Thereafter, the Exchange's circuit breaker pilot program was extended six times, most recently until October 31, 1995.[3]

The Exchange believes that its proposed rule change is consistent with Section 6 of the Act in general, and in particular, with Section 6(b)(5), in that it is designed to promote just and equitable principles of trade, prevent fraudulent and manipulative acts and practices, remove impediments to and perfect the mechanism of a free and open market and a national market system, as well as to protect investors and the public interest, by providing a reasonable means to retard a rapid, one-day market decline that can have a destabilizing effect on the nation's financial markets and the participants in these markets.

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] Securities Exchange Act Release No. 26386 (December 22, 1988), 53 FR 52904.

[3] Securities Exchange Act Release Nos. 27370 (October 23, 1989), 54 FR 43881; 28580 (October 25, 1990), 55 FR 45895; 29868 (October 28, 1991), 56 FR 56535; 26942 (November 6, 1992), 57 FR 53157; 33120 (October 29, 1993), 58 FR 59503; and 34900 (October 26, 1994), 59 FR 54932.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Phlx does not believe that the proposed rule change will impose any inappropriate burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve such proposed rule change, or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to File No. SR–Phlx–95–72 and should be submitted by October 27, 1995.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

[4] 17 CFR 200.30–3(a)(12) (1994).

Jonathan G. Katz,

Secretary.

[FR Doc. 95–24914 Filed 10–5–95; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of Reporting Requirements Submitted for Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the Federal Register notifying the public that the agency has made such a submission.

DATES: Comments should be submitted on or before November 6, 1995. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

COPIES: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Georgia Greene, Small Business Administration, 409 3rd Street, S.W., 5th Floor, Washington, D.C. 20416, Telephone: (202) 205–6629.

OMB Reviewer: Donald Arbuckle, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, D.C. 20503.

Title: Transaction Report on Loans Serviced by Lenders.

SBA Form No.: SBA Form 172.

Frequency: Monthly.

Description of Respondents: Small Business Administration participating lenders.

Annual Responses: 24,154.

Annual Burden: 3,865.

Georgia Greene,

Chief, Administrative Information Branch.

[FR Doc. 95–24865 Filed 10–5–95; 8:45 am]

BILLING CODE 8025–01–M

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of Reporting Requirements Submitted for Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the Federal Register notifying the public that the agency has made such a submission.

DATES: Comments should be submitted on or before November 6, 1995. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

COPIES: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Georgia Greene, Small Business Administration, 409 3RD Street, S.W., 5th Floor, Washington, D.C. 20416, Telephone: (202) 205–6629.

OMB Reviewer: Donald Arbuckle, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, D.C. 20503.

Title: Disclosure Statement.

SBA Form No.: SBA Form 856.

Frequency: On Occasion.

Description of Respondents: Small Business Investment Companies.

Annual Responses: 200.

Annual Burden: 200.

Georgia Greene,

Chief, Administrative Information Branch.

[FR Doc. 95–24866 Filed 10–5–95; 8:45 am]

BILLING CODE 8025–01–M

SOCIAL SECURITY ADMINISTRATION

Agency Forms Submitted to the Office of Management and Budget for Clearance

Normally on Fridays, the Social Security Administration publishes a list of information collection packages that will require submission to the Office of Management and Budget (OMB) for clearance in compliance with P.L. 96–511, as amended (P.L. 104–13 effective October 1, 1995), The Paperwork Reduction Act. Since the last list was published in the Federal Register on September 22, 1995, the following information collections have been proposed or will require extension of the current OMB approvals.

(Call the Reports Clearance Officer on (410) 965–4142 for a copy of the form(s)

or package(s), or write to her at the address listed after the information collections.)

SSA Reports Clearance Officer: Charlotte S. Whitenight.

1. Request To Be Selected As Payee—0960–0014. The information collected on form SSA–11–BK is used by the Social Security Administration to help determine the proper payee for a person who cannot receive his or her own Social Security benefits. The respondents will be individuals who apply to receive Social Security benefits on behalf of someone else.

Number of Respondents: 605,000
Frequency of Response: 1
Average Burden Per Response: 10.5 minutes
Estimated Annual Burden: 105,875 hours

2. Disability Update Report—0960–0511. The information on form SSA–455 is used by the Social Security Administration to determine if a full medical continuing disability review (CDR) should be conducted. The respondents will be Social Security disability insurance beneficiaries who are scheduled to receive a CDR.

Number of Respondents: 431,200
Frequency of Response: 1
Average Burden Per Response: 15 minutes
Estimated Annual Burden: 107,800 hours

3. Statement Regarding Marriage—0960–0017. The information collected via form SSA–753 is used by the Social Security Administration to make determinations regarding entitlement to spouse's benefits when a common law marriage is alleged. The respondents are third parties who can supply evidence concerning the existence of a common law marriage.

Number of Respondents: 40,000
Frequency of Response: 1
Average Burden Per Response: 9 minutes
Estimated Annual Burden: 6,000 hours

4. State Contribution Return—0960–0041. The information on form SSA–3961 is used by the Social Security Administration to identify and account for all contributions due and paid by the states (or interstate instrumentalities) under Section 218 of the Social Security Act. The respondents are state agencies.

Number of Respondents: 117
Frequency of Response: on occasion
Average Burden Per Response: 3 minutes
Estimated Annual Burden: 500 hours

5. Statement of Death by Funeral Director—0960–0142. The information collected on the SSA–721 is used by the Social Security Administration to verify the death of an individual insured under the Social Security Act and to determine if there is a survivor eligible for a lump sum death payment. The respondents will be funeral directors with knowledge of the death of a person insured for Social Security benefits.

Number of Respondents: 900,000
Frequency of Response: 1
Average Burden Per Response: 3.5 minutes
Estimated Annual Burden: 52,500 hours

6. Annual Report of Earnings (long and short forms)—0960–0057. The information on forms SSA–777 and SSA–7770 is used by the Social Security Administration to determine the amount of yearly earnings of beneficiaries so that the proper benefit amounts are paid to them. The respondents will be beneficiaries under age 70 who have earned over the exempt amount for the year and still received benefits.

Number of Respondents: (SSA–777)-200,000; (SSA–7770)-1,000,000

	SSA–777	SSA–7770
Frequency of Response	1	1
Average Burden Per Response	17 minutes	8 minutes.
Estimated Annual Burden	(1)190,000 hours (total for both forms).	

7. Public Information Campaigns and News Releases-0960–0544. The purpose of the public information campaigns and new releases is to better inform the public about the programs and activities of the Social Security Administration (SSA). The information is used by SSA to determine media interest in airing and printing the public information materials and news releases and to determine which materials are used, how often, its effectiveness, and the need for more local announcements. The respondents are newspapers and public broadcasting systems such as television, cable, and radio stations.

Number of Respondents: TV—500, Newspaper–500, Radio—1,500, Cable—148
Frequency of Response: Public Service Announcements—4, News Releases—Educational Tapes—2
Average Burden Per Response: 1 minute (solicitation card), 2 minutes (business reply card)
Estimated Annual Burden: 298 hours

8. Work Reintegration Study—0960–0543. The information on the two forms used in this study will aid the Social Security Administration in determining what steps it can take to help beneficiaries who are disabled due to a back condition to return to work.

Number of Respondents: 1,500
Frequency of Response: 1
Average Burden Per Response: 1 hour
Estimated Annual Burden: 1,500 hours

Social Security Administration

Written comments and recommendations regarding these information collections should be sent within 60 days from the date of this publication, directly to the SSA Reports Clearance Officer at the following address: Social Security Administration, DCFAM, Attn: Charlotte S. Whitenight, 6401 Security Blvd., 1–B–22 Operations Bldg., Baltimore, MD 21235.

In addition to your comments on the accuracy of the agency's burden estimate, we are soliciting comments on the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology.

The following information collections, which were published in the Federal Register on August 4, 1995, have been submitted to OMB:

1. Notice Regarding Substitution of Party Upon Death of Claimant—Reconsideration of Disability Cessation—OMB Control No. 0960–0351. The information on form SSA–770 is used by the Social Security Administration to obtain information from substitute parties regarding their intention to pursue the appeals process on behalf of an individual who died. The respondents are such parties.

Number of Respondents: 1,200
Frequency of Response: 1
Average Burden Per Response: 5 minutes
Estimated Annual Burden: 100 hours

2. Disability Determination and Transmittal—OMB Control No. 0960–0437. The information on form SSA–831 will be used by the State disability determination services to document whether an individual who applies for disability benefits is eligible for those benefits based on his or her alleged disability. It is also used by SSA for program management and evaluation. The respondents are state agency employees who make disability determinations for SSA.

Number of Respondents: 3,525,600
Frequency of Response: 1
Average Burden Per Response: 15 minutes
Estimated Annual Burden: 881,400

3. Cessation or Continuance of Disability or Blindness Determination and Transmittal—Title XVI—OMB Control No. 0960–0443. The information on form SSA–832 is used by State disability determination services to document determinations as to whether an individual's disability benefits should be terminated or continued on the basis of his/her impairment. The respondents are state disability determination services adjudicating Title XVI disability claims.

Number of Respondents: 53,700
Frequency of Response: 1
Average Burden Per Response: 30 minutes
Estimated Annual Burden: 26,850 hours

4. Cessation or Continuance of Disability or Blindness Determination and Transmittal—Title II—OMB Control No. 0960–0442. The information on form SSA–833 is used by State disability determination services to prepare determinations of whether individuals receiving Title II disability or blindness benefits continue to be unable to engage in substantial gainful work by reason of their impairments and are still eligible for benefit payments. It is also used to collect data for program evaluation and program management.

Number of Respondents: 268,700
Frequency of Response: 1
Average Burden Per Response: 30 minutes
Estimated Annual Burden: 134,350 hours

Social Security Administration

Written comments and recommendations regarding these information collections should be sent within 30 days of the date of this publication. Comments may be directed to OMB and SSA at the following addresses:

(OMB)
Office of Management and Budget, OIRA, Attn: Laura Oliven, New Executive Office Building, Room 10230,Washington, D.C. 20503

(SSA)
Social Security Administration, DCFAM, Attn: Charlotte S. Whitenight, 6401 Security Blvd, 1–A–21 Operations Bldg., Baltimore, MD 21235

Dated: October 2, 1995.

Charlotte Whitenight,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 95–24880 Filed 10–5–95; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration (RSPA)

Meetings of Pipeline Safety Advisory Committees

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 1) notice is hereby given of the following meetings of the Technical Hazardous Liquid Pipeline Safety Standards Committee (THLPSSC) and the Technical Pipeline Safety Standards Committee (TPSSC). Each Committee meeting, as well as a joint session of the two Committees, will be held at the McLean Hilton at Tysons Corner in McLean, VA.

On November 7, 1995, at 8:00 a.m., the members of both Committees will attend a Risk Management Conference to discuss how Government and the pipeline industry can use risk management in pipeline safety and environmental protection. More information on the Risk Management Conference was in the September 21, 1995, Federal Register (60 FR 49040).

On November 8, 1995, at 8:00 a.m., the THLPSSC will meet. Agenda items include discussion and voting on Mandatory Participation in One-Call Systems.

On November 8, 1995, at 1:00 p.m., the THLPSSC will be joined by members of the TPSSC for a joint session which will include:

1. Welcome by the RSPA Administrator
2. Welcome by Executive Director
3. Budget and Reauthorization
4. Risk Management
5. Update on the National Association of Pipeline Safety Representatives and National Association of Regulatory Utilities Commissioners
6. One-Call Campaign

On November 9, 1995, from 8:00 a.m. to 12:00 noon, the joint TPSSC-THLPSSC session will include:

1. DOT Restructuring
2. Regulatory Reinvention Initiative
3. Regulatory Updates, including Environmentally Sensitive Areas, Excess Flow Valves, Definitions of Gas Gathering Lines, Customer Owned Service Lines, Increased Inspection Requirements, and Emergency Flow Restricting Devices.

At 1:00 p.m., the TPSSC will meet. Agenda items include discussion and voting on Mandatory Participation in One-Call Systems.

Each meeting will be open to the public. Members of the public may present oral statements on the topics. Due to the limited time available, each person who wants to make an oral statement must notify Mary-Jo Cooney, Room 2335, Department of Transportation Building, 400 Seventh Street, S.W., Washington, DC 20590, telephone (202) 366–4774, not later than October 31, 1995, on the topics to be addressed and the time requested to address each topic. Members of the public may present written statements to the Committee before or after any meeting.

Issued in Washington, DC on October 2, 1995.

Cesar De Leon,

Deputy Associate Administrator for Pipeline Safety.

[FR Doc. 95–34867 Filed 10–5–95; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Fiscal Service

[Dept. Circ. 570, 1995 Rev., Supp. No. 2]

Surety Companies Acceptable on Federal Bonds, Granite Re, Inc.

A Certificate of Authority as an acceptable surety on Federal Bonds is hereby issued to the following company under Sections 9304 to 9308, Title 31, of the United States Code. Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570, 1995 Revision, on page 34441 to reflect this addition:

Granite Re, Inc. Business Address: P.O. Box 26967, Oklahoma City, OK 73126. Phone: (405) 524–7811.

Underwriting Limitation *b*/: $108,000. Surety Licenses *c*/: OK, MN, ND, SD. Incorporated In: Oklahoma.

Certificates of Authority expire on June 30 each year, unless revoked prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (31 CFR, Part 223). A list of qualified

companies is published annually as of July 1 in Treasury Department Circular 570, with details as to underwriting limitations, areas in which licenses to transact surety business and other information.

Copies of the Circular may be obtained by calling the U.S. Department of the Treasury, Financial Management Service, computerized public bulletin board system (FMS Inside Line) at (202) 874–6817/7034/6953/6872 or by purchasing a hard copy from the Government Printing Office (GPO), Washington, DC, telephone (202) 512–0132. When ordering the Circular from GPO, use the following stock number: 048–000–00489–0.

For further assistance, contact the U.S. Department of the Treasury, Financial Management Service, Funds Management Division, Surety Bond Branch, 3700 East-West Highway, Room 6F04, Hyattsville, MD 29782, telephone (202) 874–6507.

Dated: September 26, 1995.

Charles F. Schwan III,

Director, Funds Management Division, Financial Management Service.

[FR Doc. 95–24870 Filed 10–5–95; 8:45 am]

BILLING CODE 4810–35–M

Sunshine Act Meetings

Federal Register
Vol. 60, No. 194
Friday, October 6, 1995

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).

AFRICAN DEVELOPMENT FOUNDATION

Board of Directors Meeting

TIME: 11:30 a.m.-2:00 p.m.

PLACE: ADF Headquarters.

DATE: Friday, October 13, 1995.

STATUS: Open.

Agenda

11:30 a.m.: Lunch
12:00 noon: Chairman's Report
12:15 p.m.: President's Report
12:30 p.m.: Other
1:00 p.m.: Executive Session (Closed)

If you have any questions or comments, please direct them to Ms. Janis McCollim, Executive Assistant to the President, who can be reached at (202) 673-3916.

William R. Ford,

President.

[FR Doc. 95–25005 Filed 10–4–95; 10:17 am]

BILLING CODE 6116–01–P

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board; Regular Meeting

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), that the October 12, 1995 regular meeting of the Farm Credit Administration Board (Board) will not be held and that a special meeting of the Board is scheduled for Tuesday, October 24, 1995 at 10:00 a.m. An agenda for this meeting will be published at a later date.

FOR FURTHER INFORMATION CONTACT: Floyd Fithian, Secretary to the Farm Credit Administration Board, (703) 883-4025, TDD (703) 883-4444.

ADDRESS: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102-5090.

Dated: October 3, 1995.

Floyd Fithian,

Secretary, Farm Credit Administration Board.

[FR Doc. 95–25074 Filed 10–4–95; 2:53 pm]

BILLING CODE 6705–01–P

FEDERAL ELECTION COMMISSION

"FEDERAL REGISTER" NUMBER: 95–24315

PREVIOUSLY ANNOUNCED DATE AND TIME: Thursday, October 5, 1995, 10:00 a.m. Meeting open to the public.

The following items were added to the agenda pursuant to 11 CFR 2.7(d):

Establishment of Filing Requirements for the Oregon U.S. Senate Special Primary and General Elections.

MCFL Regulations:
Voter Guides.
Endorsements.

PERSON TO CONTACT FOR INFORMATION: Mr. Ron Harris, Press Officer, Telephone: (202) 219–4155.

Marjorie W. Emmons,

Secretary of the Commission.

[FR Doc. 95–25095 Filed 10–4–95; 3:35 pm]

BILLING CODE 6715–01–M

Corrections

Federal Register
Vol. 60, No. 194
Friday, October 6, 1995

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. 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 THE INTERIOR

Fish and Wildlife Service

50 CFR Part 23

RIN 1018 - AC 78

Changes in the List of Species in Appendices to the Convention on International Trade in Endangered Species of Wild Fauna and Flora

Correction

In rule document 95–24218 beginning on page 50477 in the issue of Friday, September 29, 1995, the tables on pages 50480 through 50503 are being reprinted with corrections.

Title 50—Wildlife and Fisheries

PART 23—ENDANGERED SPECIES CONVENTION

* * * * *

Subpart C—Appendices I, II and III to the Convention on International Trade in Endangered Species of Wild Fauna and Flora

* * * * *

§ 23.23 Species listed in Appendices I, II, and III.

(a) The list in this section includes species of wildlife and plants placed in Appendix I, II or III in accordance with the provisions of Articles XV and XVI of the Convention.

The list of species is organized as follows:

Major group	Subgroups
Mammals	Orders, in taxonomic sequence.
Birds	Orders, in taxonomic sequence.
Reptiles	Orders, in taxonomic sequence.
Amphibians	Orders, in taxonomic sequence.
Fishes	Orders, in taxonomic sequence.
Molluscs	Classes.
Arthropods	Classes.
Plants	Families, in alphabetical sequence.

Within each Subgroup, lower taxonomic units (mainly genera, but sometimes families or subfamilies) are listed in alphabetical sequence. Within genera, the scientific names of the species are listed in alphabetical sequence. The scientific name takes precedence over the common name in determining if a species is listed.

(b) The appendix column of the list includes the annotation ''pe'' (=possibly extinct) for certain species. It also contains the names of Parties including species in Appendix III.

(c) For purposes of issuing United States certificates of exemption under Article VII(3), the date when the Convention applies to a species is the date when the inclusion of that species in the appendices enters into force under the terms of Article XV or XVI of the Convention. The date of first listing is retained if a species is transferred from one appendix to another or if a listed species is subsequently included with other species in the listing of a taxon above the species level. Such species are shown separately in this publication of the appendices. The date of a subsequent listing is used only if a species is entirely deleted from the appendices and is subsequently reincluded after an intervening period of time.

(d) Subject to the regulations of this part are all living or dead animals or plants in Appendix I, II or III, and all their readily recognizable parts and derivatives except for (1) specified parts or derivatives of particular Appendix III animal species as excluded in the particular listing and (2) the following categorically excluded or exempted parts or derivatives of certain plants:

(1) For Appendix II and Appendix III plants and artificially propagated hybrids of Appendix I plants: Seedling or tissue cultures obtained *in vitro*, in solid or liquid media, transported in sterile containers; and

(2) For Appendix II and Appendix III plants: Seeds, spores, and pollen (including pollinia); and

(3) For artificially propagated hybrids of Appendix I plants: (i) seeds and pollen (including pollinia) and (ii) cut flowers; and:

(4) For *Panax quinquefolius* (in Araliaceae), parts and derivatives other than roots and their readily recognizable parts.

(5) For artificially propagated or naturalized Appendix II Cactaceae species: (i) fruits and their parts and derivatives; (ii) for *Opuntia* subgenus *Opuntia* species, separate stem joints (pads) and their parts and derivatives.

(6) For Orchidaceae species: (i) in Appendix I, seedling or tissue cultures obtained *in vitro*, in solid or liquid media, transported in sterile containers; (ii) in Appendix II, if artificially propagated: (A) cut flowers, and (B) for *Vanilla* species, fruits and their parts and derivatives.

(e) The list of species set out in subsection (f) is informational and not regulatory in nature. It is solely intended as a convenience to the public. The official list of species included in Appendices I, II, and III is the one maintained by the CITES Secretariat based on the decisions of the Parties to the Convention.

(f) The list of species in the Appendices to the Convention on International Trade in Endangered Species of Wild Fauna and Flora is provided below:

Species	Common name	Appendix	First listing date (month/day/year)
CLASS MAMMALIA:	MAMMALS:		
Order Monotremata:	Monotremes:		
Zaglossus spp.	Spiny anteaters	II	2/4/77
Order Dasyuromorphia:	Dunnarts (Marsupial-mice), Tasmanian wolf:		
Sminthopsis longicaudata	Long-tailed marsupial-mouse, Long-tailed dunnart.	I	7/1/75

Species	Common name	Appendix	First listing date (month/day/year)
S. psammophila	Large desert marsupial-mouse, Sandhill dunnart.	I	7/1/75
Thylacinus cynocephalus	Tasmanian wolf, Thylacine	I pe	7/1/75
Order Peramelemorphia:	Bandicoots:		
Chaeropus ecaudatus	Pig-footed bandicoot	I pe	7/1/75
Macrotis lagotis	Rabbit bandicoot, Bilby	I	7/1/75
M. leucura	Lesser rabbit bandicoot, Yallara	I	7/1/75
Perameles bougainville	Barred bandicoot, Long-nosed bandicoot, Mari.	I	7/1/75
Order Diprotodontia:	Kangaroos, Wombats, Wallabies, Cuscuses, Rat-kangaroos, etc.:		
Bettongia spp. (except species listed below)	Rat-kangaroo	I	6/28/79
B. lesueur	Lesueur's rat-kangaroo, Boodie	I	7/1/75
B. penicillata (=*tropica*)	Brush-tailed rat-kangaroo, Woylie	I	7/1/75
Burramys parvus	Mountain pigmy possum	II	7/1/75
Caloprymnus campestris	Desert rat-kangaroo	I pe	7/1/75
Dendrolagus bennettianus	Bennett's tree kangaroo, Dusky tree kangaroo.	II	6/28/79
D. inustus	Grizzled tree kangaroo	II	7/1/75
D. lumholtzi	Lumholtz's tree kangaroo	II	6/28/79
D. ursinus	Vogelkop tree kangaroo	II	7/1/75
Lagorchestes hirsutus	Western hare wallaby, Wurrup	I	7/1/75
Lagostrophus fasciatus	Banded hare wallaby, Munning	I	7/1/75
Lasiorhinus krefftii	Queensland hairy-nosed wombat	I	7/1/75
Onychogalea fraenata	Bridled nail-tailed wallaby	I	7/1/75
O. lunata	Crescent nail-tailed wallaby	I	7/1/75
Phalanger maculatus (see *Spilocuscus maculatus*)			
P. orientalis	Gray cuscus	II	6/28/79
Spilocuscus maculatus	Spotted cuscus	II	6/28/79
Order Scandentia	Tree shrews	II	2/4/77
Tupaiidae spp.	Tree shrews	II	2/4/77
Order Chiroptera:	Bats:		
Acerodon spp. (all species except those in App. I)	Flying foxes	II	1/18/90
+ A. jubatus	Golden-capped fruit bat	I	1/18/90
+ A. lucifer	Panay giant fruit bat	I pe	1/18/90
Pteropus spp. (all species except those in App. I or with earlier date in App. II).	Flying foxes	II	1/18/90
P. insularis	Truk flying fox	I	10/22/87
P. macrotis	Big-eared flying fox	II	10/22/87
P. mariannus	Mariana flying fox, Mariana fruit bat	I	10/22/87
P. molossinus	Ponape flying fox	I	10/22/87
P. phaeocephalus	Mortlock flying fox	I	10/22/87
P. pilosus	Palau flying fox	I	10/22/87
P. samoensis	Samoa flying fox	I	10/22/87
P. tokudae	Little Mariana fruit bat, Tokuda's flying fox	II	10/22/87
P. tonganus	Insular flying fox, Tonga fruit bat	I	10/22/87
Vampyrops lineatus	White-lined bat	III (Uruguay)	7/14/76
Order Primates (formerly including order Scandentia, above):	Primates: Monkeys, Apes, etc.:		
All species except those in App. I or with earlier date in App. II.		II	2/4/77
Allocebus spp.	Hairy-eared dwarf lemur	I	7/1/75
Alouatta palliata (=*villosa*)	Mantled howler monkey	I	7/1/75
A. pigra	Black howler monkey	I	7/1/75
Ateles geoffroyi frontatus	Black-handed spider monkey	I	7/1/75
A. geoffroyi panamensis	Black-handed spider monkey	I	7/1/75
Avahi spp.	Avahis, Woolly lemurs	I	7/1/75
Brachyteles arachnoides	Woolly spider monkey	I	7/1/75
Cacajao spp.	Uakaris	I	7/1/75
Callimico goeldii	Goeldi's monkey, Callimico	I	7/1/75
Callithrix aurita (=*C. jacchus aurita*)	White-eared marmoset	I	2/4/77
C. flaviceps (=*C. jacchus flaviceps*)	Buff-headed marmoset	I	2/4/77
Cebus capucinus	White-throated capuchin	II	7/1/75
Cercocebus galeritus galeritus	Tana River mangabey, Agile mangabey	I	7/1/75
Cercopithecus diana (=*C. roloway*)	Diana monkey	I	2/4/77
Cheirogaleus spp.	Dwarf lemurs	I	7/1/75
Chiropotes albinasus	White-nosed saki	I	7/1/75
Colobus (see *Procolobus*)			
Daubentonia madagascariensis	Aye-aye	I	7/1/75
Eulemur spp.	Lemurs	I	7/1/75
Gorilla gorilla	Gorilla	I	7/1/75
Hapalemur spp.	Gentle lemurs	I	7/1/75

Species	Common name	Appendix	First listing date (month/day/year)
Hylobates spp.	Gibbons, Siamang	I	7/1/75
Indri spp.	Indri	I	7/1/75
Lagothrix flavicauda	Yellow-tailed woolly monkey	I	2/4/77
Lemur spp.	Lemurs	I	7/1/75
Leontopithecus (=*Leontideus*) spp.	Golden lion tamarin	I	7/1/75
Lepilemur spp.	Sportive lemur, Weasel lemur	I	7/1/75
Loris tardigradus	Slender loris	II	7/1/75
Macaca silenus	Lion-tailed macaque	I	7/1/75
M. sylvanus	Barbary ape	II	7/1/75
Mandrillus leucophaeus	Drill	I	2/4/77
M. sphinx	Mandrill	I	2/4/77
Microcebus spp.	Mouse lemurs	I	7/1/75
Nasalis (=*Simias*) *concolor*	Pagi Island langur	I	7/1/75
N. larvatus	Proboscis monkey	I	7/1/75
Nycticebus coucang	Slow loris	II	7/1/75
Pan spp.	Chimpanzee, Bonobo	I	7/1/75
Papio (see *Mandrillus*)			
Phaner sp.	Fork mouse lemur, Fork-marked mouse lemur.	I	7/1/75
Pongo pygmaeus	Orangutan	I	7/1/75
Presbytis entellus (see *Semnopithecus entellus*)			
P. pileata (see *Trachypithecus pileatus*)			
P. potenziani	Long-tailed langur, Mentawai leaf monkey	I	2/4/77
Presbytis (other species) (see *Trachypithecus*)			
Procolobus badius gordonorum	Uhehe red colobus	II	7/1/75
P. pennantii kirki (=*C. badius kirkii*)	Zanzibar red colobus	I	7/1/75
P. rufomitratus (=*C. badius rufomitratus*)	Tana River red colobus	I	7/1/75
P. verus	Olive colobus	II	7/1/75
Propithecus spp.	Sifakas	I	7/1/75
Pygathrix (=*Rhinopithecus*) spp. (except those species with earlier date).	Snub-nosed langurs	I	2/4/77
P. nemaeus	Douc langur	I	7/1/75
P. roxellana	Sichuan snub-nosed langur	I	7/1/75
Saguinus bicolor	Pied tamarin	I	2/4/77
S. geoffroyi	Geoffroy's marmoset	I	2/4/77
S. leucopus	White-footed tamarin, Silvery-brown bare-face tamarin.	I	2/4/77
S. oedipus (including *S. oedipus geoffroyi*)	Cotton-top tamarin	I	2/4/77
Saimiri oerstedii	Red-backed squirrel monkey	I	7/1/75
Semnopithecus entellus	Gray langur, Common Indian langur	I	7/1/75
Symphalangus (see *Hylobates*)			
Trachypithecus geei	Golden langur	I	7/1/75
T. johnii	Nilgiri langur	II	7/1/75
T. pileatus	Capped langur	I	7/1/75
Tupaiidae spp. (see order Scandentia, above)			
Varecia spp.	Lemurs	I	7/1/75
Order Xenarthra:	Anteaters, Sloths, Armadillos:		
Bradypus variegatus (=*boliviensis* or *griseus*)	Three-toed sloth	II	7/1/75
Cabassous centralis	Five-toed armadillo	III (Costa Rica)	10/28/76
C. tatouay (=*gymnurus*)	Naked-tailed armadillo	III (Uruguay)	7/14/76
Choloepus hoffmanni	Two-toed sloth	III (Costa Rica)	10/28/76
Myrmecophaga tridactyla	Giant anteater	II	7/1/75
Priodontes maximus (=*giganteus*)	Giant armadillo	I	7/1/75
Tamandua tetradactyla (=*T. mexicana*)	Tamandua, Collared anteater	III (Guatemala)	4/23/81
Order Pholidota:	Pangolins, Scaly Anteaters:		
+ *Manis* spp.	Pangolins	II	7/1/75
Order Lagomorpha:	Rabbits, Hares:		
Caprolagus hispidus	Hispid hare, Assam rabbit	I	7/1/75
Romerolagus diazi	Mexican volcano rabbit	I	7/1/75
Order Rodentia:	Rodents:		
Agouti (=*Cuniculus*) *paca*	Greater paca, Spotted cavy	III (Honduras)	4/13/87
Anomalurus beecrofti	Beecroft's scaly-tailed flying squirrel	III (Ghana)	2/26/76
A. derbianus	Lord Derby's scaly-tailed flying squirrel	III (Ghana)	2/26/76
A. pelii	Pel's scaly-tailed flying squirrel	III (Ghana)	2/26/76
+ *Chinchilla* spp. (populations of South America, except domesticated specimens).	Chinchillas	I	2/4/77
Cynomys mexicanus	Mexican prairie dog	I	7/1/75
Dasyprocta punctata	Common agouti	III (Honduras)	4/13/87
Epixerus ebii	African palm squirrel	III (Ghana)	2/26/76
Hystrix cristata	Crested porcupine	III (Ghana)	2/26/76
Idiurus macrotis	Long-eared pygmy flying squirrel	III (Ghana)	2/26/76

Species	Common name	Appendix	First listing date (month/day/year)
Leporillus conditor	Australian stick-nest rat	I	7/1/75
Marmota caudata	Long-tailed marmot	III (India)	3/16/89
M. himalayana	Himalayan marmot	III (India)	3/16/89
Pseudomys praeconis	Shark Bay mouse	I	7/1/75
Ratufa spp.	Giant squirrels	II	7/1/75
Sciurus deppei	Deppe's squirrel	III (Costa Rica)	10/28/76
Sphiggurus (=*Coendou*) *mexicanus*	Middle American prehensile-tailed porcupine, Coendou.	III (Honduras)	4/13/87
S. (=*Coendou*) *spinosus*	Prehensile-tailed porcupine	III (Uruguay)	7/14/76
Xeromys myoides	False water rat	I	7/1/75
Zyzomys pedunculatus	Australian native mouse, McDonnell Range rock rat.	I	7/1/75
Order Cetacea:	Whales, Porpoises, Dolphins:		
All species except those in App. I or with earlier date in App.II.		II	6/28/79
Balaena mysticetus	Bowhead whale	I	7/1/75
Balaenoptera acutorostrata (all populations except that of West Greenland: entry into force as App. I on 1/1/86).	Minke whale	I	6/28/79
B. borealis	Sei whale	I	2/4/77
B. edeni	Bryde's whale	I	6/28/79
B. musculus	Blue whale	I	7/1/75
B. physalus	Fin whale	I	2/4/77
Berardius spp.	Beaked whales	I	6/28/79
Caperea marginata (entry into force as App. I on 1/1/86)	Pygmy right whale	I	6/28/79
Eschrichtius robustus (=*glaucus*)	Gray whale	I	7/1/75
Eubalaena (=*Balaena*)) spp.	Right whales	I	7/1/75
Hyperoodon spp.	Bottle-nosed whales	I	6/28/79
Lipotes vexillifer	White flag dolphin, Chinese river dolphin	I	6/28/79
Megaptera novaeangliae	Humpback whale	I	7/1/75
Monodon monoceros	Narwhal	II	11/16/75
Neophocaena phocaenoides	Finless porpoise	I	6/28/79
Phocoena sinus	Gulf of California harbor porpoise, Cochita	I	6/28/79
Physeter catodon (=*macrocephalus*)	Sperm whale	I	2/4/77
Platanista spp.	Ganges and Indus River dolphins	I	7/1/75
Pontoporia (=*Stenodelphis*) *blainvillei*	La Plata River dolphin	II	7/14/76
Sotalia spp.	Humpbacked dolphins	I	6/28/79
Sousa spp.	Humpbacked dolphins	I	6/28/79
Order Carnivora:	Carnivores: Cats, Bears, etc.:		
Acinonyx jubatus	Cheetah	I	7/1/75
Ailuropoda melanoleuca	Giant panda	I	3/14/84
+ Ailurus fulgens	Lesser panda	I	7/1/75
Aonyx congicus (=*microdon*) (populations of Cameroon and Nigeria).	West African ''clawless'' otter	I	7/1/75
Arctictis binturong	Binturong	III (India)	3/16/89
Bassaricyon gabbii	Bushy-tailed olingo	III (Costa Rica)	10/28/76
Bassariscus sumichrasti	Cacomistle	III (Costa Rica)	10/28/76
Canis aureus	Golden jackal	III (India)	3/16/89
C. lupus (all subspecies and populations except those listed below).	Gray wolf	II	2/4/77
C. lupus (India, Pakistan, Bhutan, and Nepal populations)	Gray wolf	I	2/4/77
C. lupus crassodon	Gray wolf, Vancouver Island gray wolf	II	7/1/75
C. lupus irremotus	Gray wolf, Rocky Mountain gray wolf	II	7/1/75
C. lupus monstrabilis	Gray wolf	II	7/1/75
C. lupus pallipes	Gray wolf, Middle East gray wolf	II	7/1/75
Caracal (=*Felis*) *caracal* (Asian population)	Caracal	I	7/1/75
Catopuma (=*Felis*) *temminckii*	Asian golden cat	I	7/1/75
Cerdocyon thous	Crab-eating fox	II	6/11/92
Chrysocyon brachyurus	Maned wolf	II	7/1/75
Civettictis (=*Viverra*) *civetta*	African civet	III (Botswana)	4/24/78
Conepatus humboldtii	Humboldt's hognose skunk	II	6/28/79
Cryptoprocta ferox	Fossa	II	2/4/77
Cuon alpinus	Dhole	II	7/1/75
Cynogale bennettii	Otter civet	II	7/1/75
Dusicyon thous (see *Cerdocyon thous)*			
Dusicyon (other species) (see *Pseudalopex*)			
Eira barbara	Tayra	III (Honduras)	4/13/87
Enhydra lutris nereis	Southern sea otter	I	7/1/75
Eupleres goudotii (=*major*)	Malagasy mongoose	II	2/4/77
Felidae spp. (all species in family except *Felis catus* or those in App. I or with earlier date in App. II).	Cats (not including House cats)	II	2/4/77

Species	Common name	Appendix	First listing date (month/day/year)
Felis (see also the following genera, formerly included in *Felis*: *Caracal*, *Catopuma*, *Herpailurus*, *Leopardus*, *Lynx*, *Oncifelis*, *Oreailurus*, *Pardofelis*, *Prionailurus*, and *Puma*)			
F. nigripes	Black-footed cat	I	7/1/75
Fossa fossana (=*fossa*)	Fanaloka	II	2/4/77
Galictis vittata (=*allamandi*)	Grison	III (Costa Rica)	10/28/76
Helarctos malayanus	Sun bear	I	7/1/75
Hemigalus derbyanus	Banded palm civet	II	2/4/77
Herpailurus (=*Felis*) *yaguarondi* (North and Central American populations).	Jaguarundi	I	7/1/75
H. yaguarondi (South American populations)	Jaguarundi	II	7/1/75
Herpestes brachyurus fusca (=*H. fuscus*)	Indian brown mongoose	III (India)	3/16/89
H. edwardsii	Indian gray mongoose	III (India)	3/16/89
H. javanicus auropunctata (=*H. auropunctatus*)	Small Indian mongoose	III (India)	3/16/89
H. smithii	Ruddy mongoose	III (India)	3/16/89
H. urva	Crab-eating mongoose	III (India)	3/16/89
H. vitticollis	Stripe-necked mongoose	III (India)	3/16/89
Hyaena (see *Parahyaena*)			
Leopardus (=*Felis*) *pardalis* (except subspecies with earlier date).	Ocelot	I	2/4/77
L. pardalis mearnsi	Ocelot	I	7/1/75
L. pardalis mitis	Brazilian ocelot	I	7/1/75
L. tigrinus (=*Felis tigrina*) (except subspecies with earlier date).	Tiger cat, Little spotted cat	I	2/4/77
L. tigrinus oncilla	Tiger cat	I	7/1/75
L. wiedii (except subspecies with earlier date)	Margay	I	2/4/77
L. wiedii nicaraguae	Central American margay	I	7/1/75
L. wiedii salvinia	Guatemalan margay	I	7/1/75
Lontra felina	Marine otter	I	7/1/75
L. longicaudis	Long-tailed otter, Neotropical otter	I	7/1/75
L. provocax	Southern river otter, South American river otter.	I	7/1/75
Lutra lutra	European river otter	I	2/4/77
Lutra (other species) (see *Lontra*)			
Lutrinae spp. (all species except those in App. I)	Otters	II	2/4/77
Lynx pardinus (=*Felis pardina*)	Spanish lynx, Iberian lynx	I	2/4/77
L. rufus (=*Felis rufa*) escuinapae	Mexican bobcat	II	7/1/75
Martes flavigula (including *M. gwatkinsi*)	Yellow-throated marten	III (India)	3/16/89
M. foina intermedia	Beech marten	III (India)	3/16/89
Mellivora capensis	Honey badger, Ratel	III (Ghana and Botswana).	2/26/76
Melursus (=*Ursus*) *ursinus*	Sloth bear	I	9/21/88
Mustela altaica	Mountain weasel	III (India)	3/16/89
M. erminea ferghanae	Ermine	III (India)	3/16/89
M. kathiah	Yellow-bellied weasel	III (India)	3/16/89
M. nigripes	Black-footed ferret	I	7/1/75
M. sibirica	Siberian weasel	III (India)	3/16/89
Nasua narica (=*nasua*)	Common coati, Coatimundi	III (Honduras)	4/13/87
N. nasua solitaria	Coatimundi	III (Uruguay)	7/14/76
Neofelis nebulosa	Clouded leopard	I	7/1/75
Oncifelis (=*Felis*) *geoffroyi*	Geoffroy's cat	I	2/4/77
Oreailurus (=*Felis*) *jacobita*	Andean cat	I	7/1/75
Paguma larvata	Masked palm civet	III (India)	3/16/89
Panthera leo persica	Asiatic lion, Indian lion	I	7/1/75
P. onca	Jaguar	I	7/1/75
P. pardus	Leopard	I	7/1/75
P. tigris	Tiger	I	7/1/75
P. uncia (see *Uncia uncia*)			
Paradoxurus hermaphroditus	Common palm civet	III (India)	3/16/89
P. jerdoni	Jerdon's palm civet	III (India)	3/16/89
+ *Parahyaena brunnea*	Brown hyaena	II	7/1/75
Pardofelis (=*Felis*) *marmorata*	Marbled cat	I	7/1/75
Potos flavus	Kinkajou	III (Honduras)	4/13/87
+ *Prionailurus* (=*Felis*) *bengalensis bengalensis* (Bangladesh, India, and Thailand populations).	Leopard cat	I	7/1/75
+ *P. bengalensis bengalensis* (all other populations)	Leopard cat	II	7/1/75
P. planiceps	Flat-headed cat	I	7/1/75
P. rubiginosus (=*Felis rubiginosa*) (Indian population)	Rusty-spotted cat	I	2/4/77
Prionodon linsang	Banded linsang	II	7/1/75
P. pardicolor	Spotted linsang	I	7/1/75
Proteles cristatus	Aardwolf	III (Botswana)	4/24/78

Species	Common name	Appendix	First listing date (month/day/year)
Pseudalopex culpaeus	Culpeo fox	II	6/28/79
P. griseus (=*fulvipes*)	Argentine gray fox	II	6/28/79
P. gymnocercus	Pampas fox	II	10/22/87
Pteronura brasiliensis	Giant otter	I	7/1/75
Puma (=*Felis*) *concolor coryi*	Florida panther, Florida puma	I	7/1/75
P. concolor costaricensis	Costa Rican puma	I	7/1/75
P. concolor couguar	Eastern puma, Adirondack cougar	I	7/1/75
Selenarctos thibetanus (see *Ursus thibetanus*)			
Speothos venaticus	Bush dog	I	2/4/77
Tremarctos ornatus	Spectacled bear	I	2/4/77
Uncia uncia	Snow leopard	I	7/1/75
Ursidae spp. (all species in family except those in App. I or with earlier date in App. II; includes Baltic States and former USSR populations).	Bears	II	6/11/92
Ursus americanus	American black bear	II	9/18/91
U. arctos (all European populations except Italian and former USSR populations).	European Brown Bear	II	7/29/83
U. arctos (Italian population)	European brown bear	II	7/1/75
U. arctos (all Asian populations, including populations of Iran, Iraq, Syria, and Turkey, except USSR populations and populations and subspecies listed in App. I).	Brown bear	II	1/18/90
U. arctos (=*U. arctos pruinosus*) (populations of Bhutan, China, and Mongolia).	Tibetan blue bear	I	7/1/75
U. arctos (all North American populations except Mexican population).	Brown bear, Grizzly	II	7/1/75
U. arctos (=*U. a. nelsoni*) (Mexican population)	Mexican grizzly bear	I	7/1/75
U. arctos isabellinus	Red bear	I	6/28/79
U. (=*Thalarctos*) *maritimus*	Polar bear	II	7/1/75
U. thibetanus (except subspecies listed below)	Asiatic black bear	I	6/28/79
U. thibetanus gedrosianus	Baluchistan black bear	I	2/4/77
Viverra civettina (=*megaspila*)	Malabar large-spotted civet	III (India)	3/16/89
V. zibetha	Large Indian civet	III (India)	3/16/89
Viverricula indica	Lesser oriental civet, Small Indian civet	III (India)	3/16/89
Vulpes bengalensis	Bengal fox	III (India)	3/16/89
V. cana	Blanford's fox	II	2/4/77
V. vulpes griffithi	Griffith's red fox	III (India)	3/16/89
V. vulpes montana	Montane red fox	III (India)	3/16/89
V. vulpes pusilla (= *leucopus*)	Little red fox	III (India)	3/16/89
V. (=*Fennecus*) *zerda*	Fennec fox	II	4/22/76
Order Pinnipedia:	Seals, Sea lions:		
Arctocephalus spp. (except species listed below)	Southern fur seals	II	2/4/77
A. australis	Southern fur seal	II	7/1/75
A. galapagoensis	Galapagos fur seal	II	7/1/75
A. philippii	Juan Fernandez fur seal	II	7/1/75
A. townsendi	Guadalupe fur seal	I	7/1/75
Mirounga leonina	Southern elephant seal	II	7/1/75
Monachus spp.	Monk seals	I	7/1/75
Odobenus rosmarus	Walrus	III (Canada)	11/16/75
Order Proboscidea:	Elephants:		
Elephas maximus	Asian elephant	I	7/1/75
Loxodonta africana	African elephant	I	2/4/77
Order Sirenia:	Dugongs, Manatees:		
Dugong dugon (except for Australian population)	Dugong	I	7/1/75
D. dugon (Australian population)	Dugong	II	7/1/75
Trichechus inunguis	South American manatee, Amazonian manatee.	I	7/1/75
T. manatus	West Indian manatee	I	7/1/75
T. senegalensis	West African manatee	II	7/1/75
Order Perissodactyla:	Odd-toed ungulates:		
Ceratotherium simum cottoni	Northern white rhinoceros	I	7/1/75
+ *C. s. simum* (population of South Africa) (no trade allowed, except for hunting trophies and for the sale of live animals to appropriate and acceptable destinations).	Southern white rhinoceros	II	2/4/77
Dicerorhinus (=*Didermocerus*) *sumatrensis*	Sumatran rhinoceros	I	7/1/75
Diceros bicornis	Black rhinoceros	I	7/1/75
Equus africanus (=*E. asinus*)	African wild ass	I	7/29/83
E. grevyi	Grevy's zebra	I	6/28/79
E. hemionus (except subspecies listed below)	Asian wild ass	II	7/1/75
E. hemionus hemionus	Asian wild ass	I	7/1/75
E. hemionus khur (see *E. onager khur*)			
E. kiang (=*hemionus*) (except subspecies listed below)	Kiang	II	7/1/75

Species	Common name	Appendix	First listing date (month/day/year)
E. kiang khur (see *E. onager khur*)			
E. onager (=hemionus) (except subspecies listed below)	Onager	II	7/1/75
E. onager khur	Onager	I	7/1/75
E. przewalskii	Przewalski's horse	I	7/1/75
E. zebra hartmannae	Hartmann's mountain zebra	II	6/28/79
E. zebra zebra	Cape mountain zebra	I	7/1/75
Rhinocerotidae spp. (all species and populations in the family except those in App. II or with earlier date in App. I).	Rhinoceroses	I	2/4/77
Rhinoceros sondaicus	Javan rhinoceros	I	7/1/75
R. unicornis	Great Indian one-horned rhinoceros	I	7/1/75
Tapirus spp. (except for species listed below)	Tapirs	I	7/1/75
T. terrestris	South American tapir	II	7/1/75
Order Artiodactyla:	Even-toed ungulates:		
Addax nasomaculatus	Addax	I	7/1/75
Ammotragus lervia	Barbary sheep, Aoudad	II	4/22/76
Antilocapra americana (Mexican population)	Mexican pronghorn	I	7/1/75
Antilope cervicapra	Blackbuck antelope	III (Nepal)	11/16/75
Axis porcinus annamiticus	Indochina hog deer	I	7/1/75
A. porcinus calamianensis	Calamianes deer	I	7/1/75
A. porcinus kuhli	Kuhl's deer, Bawean hog deer	I	7/1/75
Babyrousa babyrussa	Babirusa	I	7/1/75
Blastocerus dichotomus	Marsh deer	I	7/1/75
Bison bison athabascae	Woods bison	I	7/1/75
Boocercus (see *Tragelaphus*)			
Bos frontalis (see *B. gaurus*)			
B. gaurus	Seladang, Gaur	I	7/1/75
B. grunniens (see *B. mutus*)			
B. mutus	Wild yak	I	7/1/75
B. (=*Novibos*) *sauveli*	Kouprey	I	7/1/75
Bubalus arnee (formerly listed as *B. bubalis*, a non-protected, domesticated form).	Water buffalo	III (Nepal)	11/16/75
B. (=*Anoa*) *depressicornis*	Lowland anoa	I	7/1/75
B. (=*Anoa*) *mindorensis*	Tamaraw	I	7/1/75
B. (=*Anoa*) *quarlesi*	Mountain anoa	I	7/1/75
Budorcas taxicolor	Takin	II	8/1/85
Capra falconeri	Markhor	I	7/1/75
Capricornis sumatraensis (see *Naemorhedus sumatraensis*)			
Catagonus wagneri	Chacoan peccary, Giant peccary	I	10/22/87
Cephalophus dorsalis	Bay duiker	II	7/29/83
C. jentinki	Jentink's duiker	I	7/29/83
C. monticola	Blue duiker	II	7/1/75
C. ogilbyi	Ogilby's duiker	II	7/29/83
C. sylvicultor	Yellow-backed duiker	II	7/29/83
C. zebra	Zebra-banded duiker	II	7/29/83
Cervus dama mesopotamicus (see *Dama mesopotamica*)			
C. duvaucelii	Swamp deer	I	7/1/75
C. elaphus bactrianus	Bactrian deer	II	7/1/75
C. elaphus barbarus	Barbary deer	III (Tunisia)	4/22/76
C. elaphus hanglu	Kashmir stag	I	7/1/75
C. eldii	Eld's brow-antlered deer	I	7/1/75
C. porcinus (see *Axis porcinus*)			
Choeropsis liberiensis (see *Hexaprotodon liberiensis*)			
Dama mesopotamica	Persian fallow deer	I	2/4/77
Damaliscus dorcas dorcas (see *D. pygargus dorcas)*			
D. lunatus	Sassaby antelope, Korrigum	III (Ghana)	2/26/76
D. pygargus dorcas	Bontebok	II	7/1/75
Gazella cuvieri (=*G. gazella cuvieri*)	Mountain gazelle	III (Tunisia)	4/22/76
G. dama	Dama gazelle	I	7/29/83
G. dorcas	Dorcas gazelle	III (Tunisia)	4/22/76
G. leptoceros	Slender-horned gazelle	III (Tunisia)	4/22/76
Hexaprotodon liberiensis	Pygmy hippopotamus	II	7/1/75
Hippocamelus spp.	Huemals	I	7/1/75
+ Hippopotamus amphibius	Hippopotamus	II	2/26/76
Hippotragus niger variani	Giant sable antelope	I	7/1/75
Hyemoschus aquaticus	Water chevrotain	III (Ghana)	2/26/76
Kobus leche	Lechwe	II	7/1/75
Lama guanicoe	Guanaco	II	8/12/78
Mazama americana cerasina	Red brocket deer	III (Guatemala)	4/23/81
+ Megamuntiacus vuquanghensis	Giant muntjac	I	2/16/95
Moschus spp. (all except populations in App. I)	Musk deer	II	2/16/79
Moschus spp. (populations of Afghanistan, Bhutan, India, Myanmar, Nepal, and Pakistan).	Musk deer	I	7/1/75

Species	Common name	Appendix	First listing date (month/day/year)
Muntiacus crinifrons	Black muntjac	I	8/1/85
Naemorhedus baileyi	Goral	I	7/1/75
N. caudatus	Goral	I	7/1/75
N. sumatraensis	Serow	I	7/1/75
N. goral	Goral	I	7/1/75
Nemorhaedus (see *Naemorhedus*)			
Odocoileus virginianus mayensis	Whitetail deer	III (Guatemala)	4/23/81
Oryx dammah (=*O. tao*)	Scimitar-horned oryx	I	7/1/75
O. leucoryx	Arabian oryx	I	7/1/75
Ovis ammon (except subspecies listed below)	Argali	II	7/1/75
O. ammon hodgsonii	Tibetan argali	I	7/1/75
O. aries ophion (=*O. musimon ophion*) (see *O. orientalis ophion*)			
O. canadensis (Mexican population)	Mexican bighorn sheep	II	7/1/75
O. orientalis ophion	Cyprian red sheep	I	7/1/75
O. vignei	Shapo	I	7/1/75
Ozotoceros bezoarticus	Pampas deer	I	7/1/75
Pantholops hodgsonii	Tibetan antelope	I	7/1/75
Pecari tajacu (except populations of the United States)	Collared peccary	II	10/22/87
+ Pseudoryx nghetinhensis	Vu Quang ox	I	2/16/95
Pudu mephistophiles	Northern pudu	II	7/1/75
P. puda (=*P. pudu*)	Pudu	I	7/1/75
Rupicapra pyrenaica (=*rupicapra*) *ornata*	Apennian chamois	I	7/1/75
+ Saiga tatarica	Saiga antelope	II	2/16/95
Sus salvanius	Pygmy hog	I	7/1/75
Tayassu pecari	White-lipped peccary	II	10/22/87
T. tajacu (see *Pecari tajacu*)			
Tetracerus quadricornis	Four-horned antelope	III (Nepal)	11/16/75
Tragelaphus (=*Taurotragus*) *eurycerus*	Bongo antelope	III (Ghana)	2/26/76
T. spekii	Sitatunga antelope	III (Ghana)	2/26/76
Vicugna vicugna (except populations listed below)	Vicuna	I	7/1/75
+ V. vicugna (populations of Paranicota Province, Ia. Region of Tarapaca in Chile and all populations of Peru) (export limited to cloth products, wool sheared from live animals, and the Peruvian stock of 3249 kg. extant in November, 1994).	Vicuna	II	7/1/75
CLASS AVES:	BIRDS:		
Order Struthioniformes:	Ostriches:		
Struthio camelus (populations of Algeria, Burkina Faso, Cameroon, Central African Republic, Chad, Mali, Mauritania, Morocco, Niger, Nigeria, Senegal, and Sudan).	Ostrich	I	7/29/83
Order Rheiformes	Rheas:		
Pterocnemia pennata (see *Rhea pennata*)			
Rhea americana (all subspecies except that with earlier date in App. II).	Greater rhea, Common rhea	II	7/14/76
R. americana albescens	Greater rhea	II	7/1/75
R. pennata (except subspecies listed below)	Lesser rhea	I	6/28/79
R. pennata garleppi	Lesser rhea	I	7/1/75
R. pennata pennata	Darwin's rhea	I	7/1/75
Order Tinamiformes:	Tinamous:		
Tinamus solitarius	Solitary tinamou	I	7/1/75
Order Sphenisciformes:	Penguins:		
Spheniscus demersus	Jackass penguin, Blackfooted Cape penguin.	II	7/1/75
S. humboldti	Humboldt penguin	I	6/6/81
Order Podicipediformes:	Grebes:		
Podilymbus gigas	Atitlan grebe	I	7/1/75
Order Procellariiformes:	Albatrosses, Shearwaters, Petrels:		
Diomedea albatrus	Short-tailed albatross	I	7/1/75
Order Pelecaniformes:	Tropicbirds, Pelicans, Frigatebirds:		
Fregata andrewsi	Andrew's frigatebird	I	7/1/75
Papasula abbotti	Abbott's booby	I	7/1/75
Pelecanus crispus	Dalmatian pelican	I	7/1/75
Sula abbotti (see *Papasula abbotti*)			
Order Ciconiiformes:	Herons, Storks, Ibises, Flamingos:		
Ardea goliath	Goliath heron	III (Ghana)	2/26/76
Balaeniceps rex	Whale-headed stork	II	10/22/87
Bostrychia hagedash	Hadada ibis	III (Ghana)	2/26/76
B. rara	Spotted-breasted ibis	III (Ghana)	2/26/76
Bubulcus (=*Ardeola*) *ibis*	Cattle egret	III (Ghana)	2/26/76
Casmerodius (=*Egretta*) *albus*	Great white egret	III (Ghana)	2/26/76

Species	Common name	Appendix	First listing date (month/day/year)
Ciconia boyciana	Oriental white stork	I	7/1/75
C. ciconia boyciana (see *C. boyciana*)			
C. nigra	Black stork	II	7/1/75
Egretta garzetta	Little egret	III (Ghana)	2/26/76
Ephippiorhynchus senegalensis	Saddlebill stork	III (Ghana)	2/26/76
Eudocimus ruber	Scarlet ibis	II	10/22/87
Geronticus calvus	Southern bald ibis	II	7/1/75
G. eremita	Northern bald ibis, Hermit ibis	I	6/28/79
Hagedashia hagedash (see *Bostrychia hagedash*)			
Jabiru mycteria	Jabiru	I	8/1/85
Lampribis rara (see *Bostrychia rara*)			
Leptoptilos crumeniferus	Marabou stork	III (Ghana)	2/26/76
Mycteria cinerea	Milky wood stork	I	10/22/87
Nipponia nippon	Japanese crested ibis	I	7/1/75
Phoenicopteridae spp. (except species or populations with an earlier date in App. II).	Flamingos	II	7/29/83
Phoenicopterus andinus	Andean flamingo	II	7/1/75
P. chilensis	Chilean flamingo	II	7/1/75
P. jamesi	James flamingo	II	7/1/75
P. ruber ruber	American flamingo	II	6/28/79
Platalea leucorodia	White spoonbill	II	7/1/75
Threskiornis aethiopicus	Sacred ibis	III (Ghana)	2/26/76
Order Anseriformes:	Ducks, Geese, Swans, Screamers:		
Alopochen aegyptiacus	Egyptian goose	III (Ghana)	2/26/76
Anas acuta	Northern pintail	III (Ghana)	2/26/76
+ A. aucklandica (=*chlorotis*, =*nesiotis*)	Brown teal	I	7/1/75
A. bernieri	Madagascar teal	II	7/1/75
A. capensis	Cape wigeon	III (Ghana)	2/26/76
A. chlorotis (see *A. aucklandica*)			
A. clypeata	Northern shoveler	III (Ghana)	2/26/76
A. crecca	Green-winged teal	III (Ghana)	2/26/76
A. formosa	Baikal teal	II	6/11/92
A. laysanensis (=*A. platyrhynchos laysanensis*)	Laysan duck	I	7/1/75
A. nesiotis (see *A. aucklandica*)			
A. oustaleti (=*A. platyrhynchos oustaleti*)	Marianas mallard	I	7/1/75
A. penelope	Europeon wigeon	III (Ghana)	2/26/76
A. querquedula	Garganey	III (Ghana)	2/26/76
Aythya nyroca	White-eyed pochard	III (Ghana)	2/26/76
Branta canadensis leucopareia	Aleutian Canada goose	I	7/1/75
B. ruficollis	Red-breasted goose	II	7/1/75
B. (=*Nesochen*) *sandvicensis*	Hawaiian goose, Nene	I	7/1/75
Cairina moschata	Muscovy duck	III (Honduras)	4/13/87
C. scutulata	White-winged duck	I	7/1/75
Coscoroba coscoroba	Coscoroba swan	II	7/1/75
Cygnus melanocorypha	Black-necked swan	II	7/1/75
Dendrocygna arborea	Cuban tree duck, West Indian whistling-duck.	II	7/1/75
D. autumnalis	Black-bellied whistling-duck	III (Honduras)	4/13/87
D. bicolor (=*fulva*)	Fulvous whistling-duck	III (Ghana and Honduras).	2/26/76
D. viduata	White-faced whistling-duck	III (Ghana)	2/26/76
Nettapus auritus	African pygmy goose	III (Ghana)	2/26/76
Oxyura leucocephala	White-headed duck	II	7/29/83
Plectropterus gambensis	Spur-winged goose	III (Ghana)	2/26/76
Pteronetta hartlaubii	Hartlaub's duck	III (Ghana)	2/26/76
Rhodonessa caryophyllacea	Pink-headed duck	I pe	7/1/75
Sarkidiornis melanotos	Comb duck	II	7/1/75
Order Falconiformes:	Hawks, Falcons, Vultures, Eagles:		
All species except Cathartidae and those species in App. I or with earlier date in App. II.	All species except New World vultures	II	6/28/79
Accipitridae spp. (all South American populations)	Hawks, Harriers	II	10/28/76
Accipiter gentilis	Northern goshawk	II	2/4/77
A. gundlachi	Gundlach's hawk	II	2/4/77
A. nisus	European sparrow hawk	II	2/4/77
Aegypius monachus	European black vulture, Cinerous vulture	II	2/4/77
Aquila spp. (all species except those in App. I or with earlier date in App. II).	Eagles	II	2/4/77
A. adalberti (=*A. heliaca adalberti*)	Imperial eagle	I	2/4/77
A. chrysaetos	Golden eagle	II	7/1/75
A. heliaca	Imperial eagle	I	2/4/77
Chondrohierax uncinatus wilsonii	Cuban hook-billed kite	I	2/4/77

Species	Common name	Appendix	First listing date (month/day/year)
Circaetus spp.	Snake-eagles	II	2/4/77
Circus spp.	Harriers	II	2/4/77
Falconidae spp. (all species in family except those in App. I)	Falcons, Caracaras	II	7/1/75
Falco araea	Seychelles kestrel	I	7/1/75
F. jugger	Laggar falcon	I	7/1/75
F. newtoni (Seychelles population) (=*F.newtoni aldabranus*)	Aldabra kestrel	I	7/1/75
F. pelegrinoides (=*F. peregrinus pelegrinoides*)	Barbary falcon	I	7/1/75
F. peregrinus	Peregrine falcon	I	7/1/75
F. punctatus	Mauritius kestrel	I	7/1/75
F. rusticolus	Gyrfalcon	I	7/1/75
Gymnogyps californianus	California condor	I	7/1/75
Gypaetus barbatus	Lammergeier	II	2/4/77
Gyps fulvus	Griffon vulture	II	2/4/77
Haliaeetus spp. (except species in App. I)	Sea-eagles, Fish-eagles	II	2/4/77
H. albicilla (except subspecies listed below)	White-tailed eagle	I	2/4/77
H. albicilla greenlandicus	Greenland white-tailed sea-eagle	I	7/1/75
H. leucocephalus (except subspecies listed below)	Bald eagle	I	2/4/77
H. leucocephalus leucocephalus	Southern bald eagle	I	7/1/75
Harpia harpyja	Harpy eagle	I	7/1/75
Harpyopsis novaeguineae	New Guinea harpy eagle	II	2/4/77
Milvus milvus	Red kite	II	2/4/77
Pandion haliaetus	Osprey	II	2/4/77
Pithecophaga jefferyi	Monkey-eating eagle	I	7/1/75
Sagittarius serpentarius	Secretary bird	II	2/26/76
Sarcoramphus papa	King vulture	III (Honduras)	4/13/87
Vultur gryphus	Andean condor	I	7/1/75
Order Galliformes:	Pheasants, Curassows, Megapodes, Hoatzin:		
Aburria (see *Pipile*)			
Agelastes meleagrides	White-breasted guineafowl	III (Ghana)	2/26/76
Agriocharis ocellata	Ocellated turkey	III (Guatemala)	4/23/81
Arborophila orientalis (=*brunneopectus*)	Bar-backed partridge, Bare-throated tree-partridge.	III (Malaysia)	11/13/86
A. (=*Tropicoperdix*) *charltonii*	Scaly-breasted partridge, Chestnut-breasted tree-partridge.	III (Malaysia)	11/13/86
Argusianus argus	Great argus pheasant	II	7/1/75
Caloperdix oculea	Ferruginous wood-partridge	III (Malaysia)	11/13/86
Catreus wallichi	Cheer pheasant	I	7/1/75
Colinus virginianus ridgwayi	Masked bobwhite	I	7/1/75
Crax alberti	Blue-knobbed curassow	III (Colombia)	9/21/88
C. blumenbachii	Red-billed curassow	I	7/1/75
C. daubentoni	Yellow-knobbed curassow	III (Colombia)	9/21/88
C. globulosa	Wattled curassow	III (Colombia)	9/21/88
C. mitu mitu (see *Mitu mitu mitu*)			
C. pauxi (see *Pauxi pauxi*)			
C. rubra	Great curassow	III (Colombia, Costa Rica, Guatemala, and Honduras).	10/28/76
Crossoptilon crossoptilon	White-eared pheasant	I	7/1/75
C. harmani (=*C. crossoptilon harmani*)	Elwes's eared-pheasant	I	7/1/75
C. mantchuricum	Brown-eared pheasant	I	7/1/75
Gallus sonneratii	Gray jungle fowl	II	7/1/75
Ithaginis cruentus	Blood pheasant	II	7/1/75
Lophophorus impejanus	Himalayan monal	I	7/1/75
L. lhuysii	Chinese monal	I	7/1/75
L. sclateri	Sclater's monal	I	7/1/75
Lophura edwardsi	Edward's pheasant	I	7/1/75
L. erythrophthalma	Crestless fireback	III (Malaysia)	11/13/86
L. ignita	Crested fireback	III (Malaysia)	11/13/86
L. imperialis	Imperial pheasant	I	7/1/75
L. swinhoii	Swinhoe's pheasant	I	7/1/75
Macrocephalon maleo	Maleo megapode	I	7/1/75
Melanoperdix nigra	Black wood-partridge	III (Malaysia)	11/13/86
Mitu mitu mitu	Mitu, Razor-billed curassow	I	7/1/75
Oreophasis derbianus	Horned guan	I	7/1/75
Ortalis vetula	Plain chachalaca	III (Guatemala, Honduras).	4/23/81
Pauxi pauxi	Northern helmeted curassow	III (Colombia)	9/21/88
Pavo muticus	Green peafowl	II	2/4/77

Species	Common name	Appendix	First listing date (month/day/year)
Penelope albipennis	White-winged guan	I	6/6/81
P. purpurascens	Northern crested guan	III (Honduras)	4/13/87
Penelopina nigra	Black chachalaca, Highland guan	III (Guatemala)	4/23/81
Pipile jacutinga	Black-fronted piping-guan	I	7/1/75
P. pipile pipile	Trinidad white-headed curassow	I	7/1/75
Polyplectron bicalcaratum	Gray peacock-pheasant	II	7/1/75
P. emphanum	Palawan peacock-pheasant	I	7/1/75
P. germaini	Germain's peacock-pheasant	II	7/1/75
P. inopinatum	Rothschild's peacock-pheasant, Mountain peacock pheasant.	III (Malaysia)	11/13/86
P. malacense	Malaysian peacock-pheasant	II	7/1/75
P. schleiermacheri (=*P. malacense schleiermacheri*)	Bornean peacock-pheasant	II	7/1/75
Rheinardia ocellata (=*R. nigrescens*)	Rheinard's crested argus, Crested argus pheasant.	I	11/13/86
Rhizothera longirostris	Long-billed wood-partridge	III (Malaysia)	11/13/86
Rollulus roulroul	Crested wood-partridge, Roulroul, Green-winged wood partridge.	III (Malaysia)	11/13/86
Syrmaticus ellioti	Elliot's pheasant	I	7/1/75
S. humiae	Bar-tailed pheasant	I	7/1/75
S. mikado	Mikado pheasant	I	7/1/75
Tetraogallus caspius	Caspian snowcock	I	7/1/75
T. tibetanus	Tibetan snowcock	I	7/1/75
Tragopan blythii	Blyth's tragopan	I	7/1/75
T. caboti	Cabot's tragopan	I	7/1/75
T. melanocephalus	Western tragopan	I	7/1/75
T. satyra	Satyr tragopan	III (Nepal)	11/16/75
Tympanuchus cupido attwateri	Attwater's greater prairie chicken	I	7/1/75
Order Gruiformes:	Cranes, Rails, Bustards:		
Anthropoides (see *Grus*)			
Ardeotis nigriceps	Great Indian bustard	I	7/1/75
Balearica regulorum	Crowned crane	II	7/1/75
Chlamydotis undulata	Houbara bustard	I	7/1/75
Choriotis (see *Ardeotis*)			
Eupodotis bengalensis	Bengal florican	I	7/1/75
Gallirallus australis hectori	Eastern weka rail	II	7/1/75
G. sylvestris	Lord Howe wood rail	I	7/1/75
Gruidae spp. (all species and subspecies except those in App. I and those with earlier date in App. II).	Cranes	II	8/1/85
Grus americana	Whooping Crane	I	7/1/75
G. canadensis nesiotes	Cuba sandhill crane	I	7/1/75
G. canadensis pratensis	Florida sandhill crane	II	7/1/75
G. canadensis pulla	Mississippi sandhill crane	I	7/1/75
G. japonensis	Manchurian crane	I	7/1/75
G. leucogeranus	Siberian white crane	I	7/1/75
G. monacha	Hooded crane	I	7/1/75
G. nigricollis	Black-necked crane	I	7/1/75
G. vipio	White-naped crane	I	7/1/75
G. virgo	Demoiselle crane	II	7/29/83
Houbaropsis (see *Eupodotis*)			
Otididae spp. (all species except those in App. I or with earlier date in App. II).	Bustards	II	10/22/87
Otis tarda	Great bustard	II	7/1/75
Pedionomus torquatus	Collared hemipode, Plains wanderer	II	6/28/79
Rhynochetos jubatus	Kagu	I	7/1/75
Tricholimnas sylvestris (see *Gallirallus sylvestris*)			
Turnix melanogaster	Black-breasted button-quail	II	6/28/79
Order Charadriiformes:	Shorebirds, Gulls, Terns, Skimmers, Auks:		
Burhinus bistriatus	Double-striped thick-knee, Mexican stone curlew.	III (Guatemala)	4/23/81
Larus relictus	Relict gull	I	7/1/75
Numenius borealis	Eskimo curlew	I	7/1/75
N. tenuirostris	Slender-billed curlew	I	7/1/75
Tringa guttifer	Nordmann's greenshank	I	7/1/75
Order Columbifomes:	Pigeons, Doves, Sand-grouse:		
Caloenas nicobarica	Nicobar pigeon	I	6/28/79
Columba guinea	Speckled pigeon	III (Ghana)	2/26/76
C. iriditorques	Bronze-necked pigeon, Bronze-naped pigeon.	III (Ghana)	2/26/76
C. livia	Rock dove	III (Ghana)	2/26/76
C. mayeri	Pink pigeon	III (Mauritius)	12/4/75
C. unicincta	African wood pigeon	III (Ghana)	2/26/76

Species	Common name	Appendix	First listing date (month/day/year)
Ducula mindorensis	Mindoro imperial pigeon	I	7/1/75
Gallicolumba luzonica	Bleeding-heart pigeon	II	7/1/75
Goura spp.	Crowned pigeons	II	7/1/75
Nesoenas mayeri (see *Columba mayeri*)			
Oena capensis	Namaqua dove, Masked dove	III (Ghana)	2/26/76
Streptopelia decipiens	African mourning dove, Mourning collared dove.	III (Ghana)	2/26/76
S. roseogrisea	African turtle dove, African collared dove	III (Ghana)	2/26/76
S. semitorquata	Red-eyed dove	III (Ghana)	2/26/76
S. senegalensis	Laughing dove	III (Ghana)	2/26/76
S. turtur	Turtle dove	III (Ghana)	2/26/76
S. vinacea	Vinaceous dove	III (Ghana)	2/26/76
Treron calva	African green pigeon	III (Ghana)	2/26/76
T. waalia	Yellow-bellied green pigeon	III (Ghana)	2/26/76
Turtur abyssinicus	Black-billed wood dove	III (Ghana)	2/26/76
T. afer	Blue-spotted wood dove	III (Ghana)	2/26/76
T. brehmeri	Blue-headed wood dove	III (Ghana)	2/26/76
T. tympanistria	Tambourine dove	III (Ghana)	2/26/76
Order Psittaciformes:	Parrots, Parakeets, Macaws, Lories:		
All species in order except those in App. I or with earlier date in App. II, and except *Melopsittacus undulatus, Nymphicus hollandicus*, and *Psittacula krameri*. However, the latter is listed separately in App. III.	All Parrots, Parakeets, Macaws and Lories (not including the Budgerigar, Cockatiel, and Rose-ringed parakeet).	II	6/6/81
Amazona arausiaca	Red-necked parrot	I	6/6/81
A. barbadensis	Yellow-shouldered parrot	I	6/6/81
A. brasiliensis	Red-tailed parrot	I	6/6/81
A. dufresniana rhodocorytha (see *A. rhodocorytha*)			
A. guildingii	St. Vincent parrot	I	7/1/75
A. imperialis	Imperial parrot, Sisserou	I	7/1/75
A. leucocephala	Cuban parrot	I	7/1/75
A. pretrei	Red-spectacted parrot	I	7/1/75
A. rhodocorytha	Red-browed parrot	I	7/1/75
A. tucumana	Tucuman parrot	I	6/6/81
A. versicolor	St. Lucia parrot	I	7/1/75
A. vinacea	Vinaceous parrot	I	7/1/75
A. vittata	Puerto Rican parrot	I	7/1/75
Anodorhynchus glaucus	Glaucous macaw	I	7/1/75
A. hyacinthinus	Hyacinth macaw	I	6/6/81
A. leari	Lear's macaw, Indigo macaw	I	7/1/75
Ara ambigua	Buffon's macaw, Great green macaw	I	10/28/76
A. glaucogularis	Caninde macaw	I	6/6/81
A. macao	Scarlet macaw	I	10/28/76
A. maracana	Illiger's macaw	I	6/6/81
A. militaris	Military macaw	I	6/6/81
A. rubrogenys	Red-fronted macaw	I	6/6/81
Aratinga guarouba	Golden parakeet	I	7/1/75
Cacatua goffini	Goffin's cockatoo	I	6/6/81
C. haematuropygia	Red-vented cockatoo	I	6/6/81
C. moluccensis	Moluccan cockatoo	I	6/6/81
C. (=*Kakatoe*) *tenuirostris*	Long-billed corella, Slender-billed cockatoo.	II	2/4/77
Calyptorhynchus lathami	Glossy black cockatoo	II	2/4/77
Coracopsis nigra (Seychelles population)	Seychelles vasa parrot	II	7/1/75
Cyanoliseus patagonus byroni	Burrowing parakeet	II	6/28/79
Cyanopsitta spixii	Spix's macaw	I	7/1/75
Cyanoramphus auriceps forbesi	Forbes' parakeet, Yellow-fronted parakeet	I	7/1/75
C. auriceps malherbi	Orange-fronted parakeet	II	7/1/75
C. cookii	Norfolk parakeet	I	7/1/75
C. malherbi (see *C. auriceps malherbi*)			
C. novaezelandiae	New Zealand parakeet, Red-fronted parakeet.	I	7/1/75
C. unicolor	Antipodes green parakeet	II	7/1/75
Cyclopsitta diophthalma coxeni	Coxen's fig parrot	I	2/4/77
+ Eos histrio	Red and blue lory	I	6/6/81
Eunymphicus cornutus	Horned parakeet	II	7/1/75
Geopsittacus occidentalis (see *Pezoporus occidentalis*)			
Neophema chrysogaster	Orange-bellied parakeet	I	7/1/75
N. splendida	Scarlet-chested parakeet	II	7/1/75
Northiella haematogaster narethae	Blue-bonnet parrot	II	2/4/77
Ognorhynchus icterotis	Yellow-eared parrot	I	6/6/81
Opopsitta (see *Cyclopsitta*)			

Species	Common name	Appendix	First listing date (month/day/year)
Pezoporus occidentalis	Night parrot, Australian night parrot	I pe	7/1/75
P. wallicus	Ground parrot	I	2/4/77
Pionopsitta pileata	Red-capped parrot, Pileated parrot	I	7/1/75
Poicephalus robustus	Cape parrot	II	7/1/75
Polytelis alexandrae	Princess parrot	II	2/4/77
Probosciger aterrimus	Great black cockatoo, Palm cockatoo	I	7/1/75
Prosopeia personata	Masked shining parrot, Yellow-breasted musk parrot.	II	7/1/75
Psephotus chrysopterygius	Golden-shouldered parakeet	I	7/1/75
P. dissimilis	Hooded parrot	I	7/1/75
P. pulcherrimus	Paradise parakeet	I pe	7/1/75
P. haematogaster narethae (see *Northiella*)			
Psittacula echo (=*P. krameri echo*)	Rose-ringed parakeet	I	7/1/75
P. krameri	Ring-neck parakeet	III (Ghana)	2/26/76
+ Psittacus erithacus princeps	Principe parrot	II	7/1/75
Pyrrhura cruentata	Blue-throated parakeet, Ochre-marked parakeet.	I	7/1/75
Rhynchopsitta pachyrhyncha	Thick-billed parrot	I	7/1/75
R. terrisi (=*R. pachyrhyncha terrisi*)	Maroon-fronted parrot	I	6/6/81
Strigops habroptilus	Kakapo, Owl parrot	I	7/1/75
Tanygnathus lucionensis	Blue-naped parrot	II	2/4/77
Order Cuculiformes:	Cuckoos, Plantain-eaters, Turacos:		
Corythaeola cristata	Great blue turaco	III (Ghana)	2/4/77
Crinifer piscator	Gray plantain eater	III (Ghana)	2/4/77
Musophaga (=*Tauraco*, =*Gallirex*) *porphyreolopha*	Violet-crested turaco	II	7/1/75
M. violacea	Violet turaco	III (Ghana)	2/4/77
+ Tauraco spp. (except those with earlier date in App. II or III).	Turacos, Louries	II	2/16/95
T. corythaix	Knysna turaco	II	2/4/77
T. macrorhynchus	Yellow-billed turaco	II	2/4/77
Order Strigiformes:	Owls:		
All species except those in App. I or with earlier date in App. II.		II	6/28/79
Athene blewitti	Forest little owl, Forest spotted owlet	I	6/28/79
Bubo ascalaphus	Pharaoh eagle owl	II	2/4/77
B. bengalensis	Rock eagle owl	II	2/4/77
B. bubo	Eurasian eagle owl	II	2/4/77
Mimizuku gurneyi	Giant scops owl	I	7/1/75
Ninox novaeseelandiae undulata	Great hawk-owl	I	2/4/77
N. squamipila natalis	Great hawk-owl, Moluccan hawk-owl	I	2/4/77
Nyctea scandiaca	Snowy owl	II	2/4/77
Otus gurneyi (see *Mimizuku gurneyi*)			
O. nudipes newtoni	Virgin Island screech owl	II	7/1/75
Strigidae (all species native to Ghana)	Owls	II	2/26/76
Strix butleri	Hume's wood owl	II	2/4/77
S. nebulosa	Great gray owl	II	11/16/75
Tytonidae (all species native to Ghana)	Barn owls	II	2/26/76
Tyto soumagnei	Madagascar red owl	I	2/4/77
Order Apodiformes:	Swifts, Hummingbirds:		
Glaucis (see *Ramphodon*)			
Ramphodon dohrnii	Hook-billed hermit	I	7/1/75
Trochilidae spp.	Hummingbirds	II	10/22/87
Order Trogoniformes:	Trogons:		
Pharomachrus mocinno	Resplendent quetzal	I	7/1/75
Order Coraciiformes:	Hornbills, Kingfishers, Rollers, Bee-eaters, Motmots:		
Aceros spp. (all species except those in App. I or with earlier date in App. II).	Hornbills	II	6/11/92
A. narcondami	Narcondam hornbill	II	7/1/75
A. nipalensis	Rufous-necked hornbill	I	6/11/92
A. subruficollis	Plain-pouched hornbill	I	6/11/92
Anorrhinus (=*Ptilolaemus*) spp.	Hornbills	II	6/11/92
Anthracoceros spp.	Hornbills, Pied hornbills	II	6/11/92
Buceros spp. (all species and subspecies except those in App. I or with earlier date in App. II).	Giant hornbills	II	6/11/92
B. bicornis	Great hornbill	I	7/1/75
B. hydrocorax hydrocorax	Luzon-Marinduque rufous hornbill	II	7/1/75
B. rhinoceros (except subspecies with earlier date)	Rhinoceros hornbill	II	1/18/90
B. rhinoceros rhinoceros	Malay rhinoceros hornbill	II	7/1/75
B. (=*Rhinoplax*) *vigil*	Helmeted hornbill	I	7/1/75
Penelopides spp.	Hornbills	II	6/11/92

Species	Common name	Appendix	First listing date (month/day/year)
Order Piciformes:	Woodpeckers, Toucans, Jacamars, Barbets:		
Baillonius bailloni	Saffron toucanet	III (Argentina)	6/11/92
Campephilus imperialis	Imperial woodpecker	I	7/1/75
Dryocopus javensis richardsi	Tristam's white-bellied woodpecker	I	7/1/75
Pteroglossus aracari	Black-necked aracari	II	6/11/92
P. castanotis	Chestnut-eared aracari	III (Argentina)	6/11/92
P. viridis	Green aracari	II	6/11/92
Ramphastos dicolorus	Red-breasted toucan	III (Argentina)	6/11/92
R. sulphuratus	Keel-billed toucan	II	4/23/81
R. toco	Toco toucan	II	6/11/92
R. tucanus	Red-billed toucan	II	6/11/92
R. vitellinus	Channel-billed toucan	II	6/11/92
Selenidera maculirostris	Spot-billed toucanet	III (Argentina)	6/11/92
Semnornis ramphastinus	Toucan barbet	III (Colombia)	5/28/89
Order Passeriformes:	Perching birds, Songbirds:		
+ *Agelaius* (=*Xanthopsar*) *flavus*	Saffron-cowled blackbird	I	7/14/76
Amadina fasciata	Cut-throat	III (Ghana)	2/26/76
Amandava subflava	Zebra waxbill	III (Ghana)	2/26/76
Amblyospiza albifrons	Grosbeak weaver	III (Ghana)	2/26/76
Anaplectes rubriceps	Red-headed malimbe	III (Ghana)	2/26/76
Anomalospiza imberbis	Parasitic weaver	III (Ghana)	2/26/76
Atrichornis clamosus	Noisy scrub-bird	I	7/1/75
Bebrornis rodericanus	Rodriquez Island warbler	III (Mauritius)	12/4/75
Bubalornis albirostris	Buffalo weaver	III (Ghana)	2/26/76
Carduelis (=*Spinus*) *cucullata*	Red siskin	I	7/1/75
C. (=*Spinus*) *yarrellii*	Yellow-faced siskin	II	7/1/75
Cephalopterus ornatus	Amazonian umbrellabird	III (Colombia)	9/21/88
C. penduliger	Long-wattled umbrellabird	III (Colombia)	9/21/88
Cotinga maculata	Banded cotinga	I	7/1/75
Cyornis ruckii	Rueck's blue flycatcher, Niltava	II	7/1/75
Dasyornis broadbenti litoralis	Western rufous bristlebird	I pe	7/1/75
D. longirostris (=*D. brachypterus longirostris*)	Western bristlebird	I	7/1/75
Estrilda astrild	Common waxbill	III (Ghana)	2/26/76
E. caerulescens	Lavender waxbill, Lavender fire-finch	III (Ghana)	2/26/76
E. melpoda	Orange-cheeked waxbill	III (Ghana)	2/26/76
E. troglodytes	Black-rumped waxbill	III (Ghana)	2/26/76
Euplectes afer	Yellow-crowned bishop	III (Ghana)	2/26/76
E. ardens	Red-collared whydah	III (Ghana)	2/26/76
E. franciscanus	Red bishop, Orange bishop	III (Ghana)	2/26/76
E. hordeaceus	Black-winged red bishop	III (Ghana)	2/26/76
E. macrourus	Yellow-mantled whydah	III (Ghana)	2/26/76
E. orix (see *E. franciscanus*)			
Gracula religiosa	Hill myna	III (Thailand)	6/11/92
Gubernatrix cristata	Yellow cardinal	II	7/14/76
Lagonosticta larvata (see *L. vinacea*)			
L. rara	Black-bellied waxbill	III (Ghana)	2/26/76
L. rubricata	African waxbill	III (Ghana)	2/26/76
L. rufopicta	Bar-breasted waxbill	III (Ghana)	2/26/76
L. senegala	Red-billed fire finch, Red-billed waxbill	III (Ghana)	2/26/76
L. vinacea	Vinaceous waxbill	III (Ghana)	2/26/76
Leucopsar rothschildi	Rothschild's starling, Myna	I	7/1/75
Lichenostomus melanops cassidix	Helmeted honeyeater	I	7/1/75
Lonchura bicolor	Black-and white mannikin	III (Ghana)	2/26/76
L. cantans	White-throated munia, African silverbill	III (Ghana)	2/26/76
L. cucullata	Bronze mannikin	III (Ghana)	2/26/76
L. fringilloides	Magpie mannikin, Pied mannikin	III (Ghana)	2/26/76
L. malabarica (see *L. cantans*)			
Malimbus cassini	Cassin's malimbe	III (Ghana)	2/26/76
M. malimbicus	Crested malimbe	III (Ghana)	2/26/76
M. nitens	Gray's malimbe	III (Ghana)	2/26/76
M. rubriceps (see *Anaplectes rubriceps*)			
M. rubricollis	Red-headed weaver	III (Ghana)	2/26/76
M. scutatus	Red-vented malimbe	III (Ghana)	2/26/76
Mandingoa nitidula	Green-backed twin-spot	III (Ghana)	2/26/76
Meliphaga cassidix (see *Lichenostomus melanops cassidix*)			
Nesocharis capistrata	Gray-headed olive-back	III (Ghana)	2/26/76
Nigrita bicolor	Chestnut-breasted negro-finch	III (Ghana)	2/26/76
N. canicapilla	Gray-headed negro-finch	III (Ghana)	2/26/76
N. fusconota	White-breasted negro-finch	III (Ghana)	2/26/76
N. luteifrons	Pale-fronted negro-finch	III (Ghana)	2/26/76
Niltava (=*Muscicapa*) (see *Cyornis*)			

Species	Common name	Appendix	First listing date (month/day/year)
Ortygospiza atricollis	Common quail-finch	III (Ghana)	2/26/76
Pachyphantes superciliosus	Compact weaver	III (Ghana)	2/26/76
Paradiseidae spp. (all species in family)	Birds of paradise	II	7/1/75
Parmoptila rubrifrons (=*woodhousei*)	Jameson's antpecker, Flowerpecker weaver-finch.	III (Ghana)	2/26/76
Paroaria capitata	Yellow-billed cardinal	II	10/22/87
P. coronata	Red-crested cardinal	II	10/22/87
Passer griseus	Gray-headed sparrow	III (Ghana)	2/26/76
Petronia dentata	Bush petronia	III (Ghana)	2/26/76
Pholidornis rushiae	Tit-hylia	III (Ghana)	2/26/76
Picathartes gymnocephalus	Bare-headed rockfowl, White-necked rockfowl.	I	7/1/75
P. oreas	Gray-necked rockfowl, Red-headed rockfowl.	I	7/1/75
Pitta brachyura nympha (see *P. nympha*)			
P. guajana	Blue-tailed pitta, Banded pitta	II	12/7/87
P. gurneyi	Gurney's pitta	I	12/7/87
P. kochi	Koch's pitta	I	7/1/75
P. nympha	Fairy pitta, Blue-winged pitta	II	7/1/75
Plocepasser superciliosus	Chestnut-crowned sparrow-weaver	III (Ghana)	2/26/76
Ploceus albinucha	White-naped black weaver	III (Ghana)	2/26/76
P. aurantius	Orange weaver	III (Ghana)	2/26/76
P. cucullatus	Black-headed weaver	III (Ghana)	2/26/76
P. heuglini	Heuglin's masked weaver	III (Ghana)	2/26/76
P. luteolus	Little weaver	III (Ghana)	2/26/76
P. melanocephalus	Yellow-backed weaver	III (Ghana)	2/26/76
P. nigerrimus	Viellot's weaver	III (Ghana)	2/26/76
P. nigricollis	Black-necked weaver	III (Ghana)	2/26/76
P. pelzelni	Slender-billed weaver	III (Ghana)	2/26/76
P. preussi	Golden-backed weaver	III (Ghana)	2/26/76
P. superciliosus (see *Pachyphantes superciliosus*)			
P. tricolor	Yellow-mantled weaver	III (Ghana)	2/26/76
P. vitellinus (=*P. velatus*)	Vitelline masked weaver	III (Ghana)	2/26/76
Poephila cincta cincta	Black-throated finch, Parson finch	II	10/17/80
Pseudochelidon sirintarae	White-eyed river martin	I	7/1/75
Pyrenestes ostrinus	Black-bellied seedcracker	III (Ghana)	2/26/76
Pytilia hypogrammica	Yellow-winged pytilia	III (Ghana)	2/26/76
P. phoenicoptera	Red-winged pytilia	III (Ghana)	2/26/76
Quelea erythrops	Red-headed quelea	III (Ghana)	2/26/76
Rupicola spp.	Cocks-of-the-rock	II	7/1/75
Serinus canicapillus (=*gularis*)	West African seedeater	III (Ghana)	2/26/76
S. leucopygius	White-rumped seedeater	III (Ghana)	2/26/76
S. mozambicus	Yellow-fronted canary	III (Ghana)	2/26/76
Spermophaga haematina	Blue-bill	III (Ghana)	2/26/76
Sporopipes frontalis	Speckled-fronted weaver	III (Ghana)	2/26/76
Tchitrea (see *Terpsiphone*)			
Terpsiphone bourbonnensis	Coq de Boise, Mascarene paradise flycatcher.	III (Mauritius)	12/4/75
Uraeginthus bengalus	Red-cheeked cordon-bleu	III (Ghana)	2/26/76
Vidua (=*Hypochera*) *chalybeata*	Village indigobird	III (Ghana)	2/26/76
V. interjecta	Uelle paradise whydah	III (Ghana)	2/26/76
V. larvaticola	Bako indigobird	III (Ghana)	2/26/76
V. macroura	Pin-tailed whydah	III (Ghana)	2/26/76
V. orientalis (=*paradisaea*)	Northern paradise whydah	III (Ghana)	2/26/76
V. raricola	Jambandu indigobird	III (Ghana)	2/26/76
V. togoensis	Togo paradise whydah	III (Ghana)	2/26/76
V. wilsoni	Wilson's indigobird	III (Ghana)	2/26/76
Xanthopsar (see *Agelaius*)			
Xipholena atropurpurea	White-winged cotinga	I	7/1/75
Zosterops albogularis	White-chested white-eye, Norfolk Island white-eye.	I	7/1/75
CLASS REPTILIA:	REPTILES:		
Order Testudinata:	Turtles, Tortoises:		
Batagur baska	River terrapin, Tuntong	I	7/1/75
Cheloniidae spp. (all species in family)	Sea turtles	I	7/1/75
Chersina (=*Testudo*) spp.	Bow-sprit tortoises	II	7/1/75
Clemmys insculpta	Wood turtle	II	6/11/92
C. muhlenbergi	Bog turtle	I	7/1/75
Dermatemys mawii	Central American river turtle	II	6/6/81
Dermochelys coriacea	Leatherback sea turtle	I	7/1/75
Erymnochelys madagascariensis	Madagascar turtle	II	7/1/75

Species	Common name	Appendix	First listing date (month/day/year)
Geochelone spp. (except species listed below)	Land tortoises	II	7/1/75
G. (=*Testudo*) *nigra* (=*elephantopus*)	Galapagos tortoise	I	7/1/75
G. (=*Testudo*) *radiata*	Madagascar radiated tortoise	I	7/1/75
G. (=*Testudo*) *yniphora*	Angulated tortoise	I	7/1/75
Geoclemys (=*Damonia*) *hamiltonii*	Spotted pond turtle	I	7/1/75
Gopherus spp. (except species listed below)	Gopher tortoises	II	7/1/75
G. flavomarginatus	Bolson tortoise	I	7/1/75
Homopus spp.	African parrot-beaked tortoises	II	7/1/75
Kachuga tecta	Indian sawback turtle	I	7/1/75
Kinixys spp.	Hinged-back tortoise	II	7/1/75
+ *Lissemys punctata* (all subspecies except *punctata*)	Indian flap-shell tortoise	II	2/16/95
+ *L. p. punctata*	Indian flap-shell tortoise	II	7/1/75
Malacochersus spp.	Pancake tortoises	II	7/1/75
Melanochelys (=*Geoemyda*) *tricarinata*	Three-keeled Asian turtle	I	7/1/75
Morenia ocellata	Burmese peacock turtle	I	7/1/75
Pelomedusa subrufa	Helmeted terrapin	III (Ghana)	2/26/76
Peltocephalus dumeriliana	Big-headed Amazon River turtle	II	7/1/75
Pelusios adansonii	Adanson's hinged terrapin	III (Ghana)	2/26/76
P. castaneus	Brown hinged terrapin, Swamp hinged terrapin.	III (Ghana)	2/26/76
P. gabonensis	Gabon hinged terrapin	III (Ghana)	2/26/76
P. niger	Black hinged terrapin	III (Ghana)	2/26/76
Podocnemis spp.	South American turtles	II	7/1/75
Psammobates (=*Testudo*) *geometricus*	Geometric turtle	I	2/4/77
Pseudemydura umbrina	Short-necked swamp turtle	I	7/1/75
Pyxis spp.	Madagascar spider tortoises	II	7/1/75
+ *Terrapene* spp. (all species except those in App. I)	Box turtles	II	2/16/95
T. coahuila	Aquatic box turtle	I	7/1/75
Testudinidae spp. (all species except those in App. I or with earlier date in App. II).	Land tortoises	II	2/4/77
Testudo spp. (all species except those in App. I)	Land tortoises	II	7/1/75
+ *T. kleinmanni*	Egyptian tortoise	I	2/4/77
Trionyx ater	Cuatro Cienegas softshell turtle	I	7/1/75
T. gangeticus	Indian softshell turtle	I	7/1/75
T. hurum	Peacock softshell turtle	I	7/1/75
T. nigricans	Black softshell turtle	I	7/1/75
T. triunguis	Three-clawed turtle	III (Ghana)	2/26/76
Order Crocodylia:	Crocodiles, Alligators, Caimans, Gavials:		
Alligatoridae spp. (all species in family except those in App. I or with earlier date in App. II).	Alligators, Caimans	II	2/4/77
Alligator mississippiensis	American alligator	II	7/1/75
A. sinensis	Chinese alligator	I	7/1/75
Caiman crocodilus apaporiensis	Apaporis River caiman	I	7/1/75
C. crocodilus crocodilus	Common caiman, Spectacled caiman	II	7/1/75
C. crocodilus fuscus (including *C. crocodilus chiapasius*)	Brown caiman	II	7/1/75
C. crocodilus yacare (=*C. yacare*)	Yacare	II	7/1/75
C. latirostris	Broad-snouted caiman	I	7/1/75
Crocodylidae spp. (all species in family except those in App. I or with earlier date in App. II).	Crocodiles	II	2/4/77
Crocodylus acutus	American crocodile	I	7/1/75
C. cataphractus	African slender-snouted crocodile	I	7/1/75
C. intermedius	Orinoco crocodile	I	7/1/75
C. johnsoni	Johnson's crocodile	II	7/1/75
C. moreletii	Morelet's crocodile	I	7/1/75
C. niloticus (except those populations in App. II)	Nile crocodile	I	7/1/75
+ *C. niloticus* (populations of Madagascar and Uganda subject to export quotas described by the Secretariat).	Nile crocodile	II	7/1/75
+ *C. niloticus* (populations of Botswana, Ethiopia, Kenya, Malawi, Mozambique, South Africa, Zambia, and Zimbabwe subject to ranching provisions).	Nile crocodile	II	7/1/75
+ *C. niloticus* (population of Tanzania subject to ranching provisions and annual quotas described by the Secretariat).	Nile crocodile	II	7/1/75
C. novaeguineae (except subspecies listed below)	New Guinea crocodile, Freshwater crocodile.	II	7/1/75
C. novaeguineae mindorensis	Philippine crocodile	I	7/1/75
C. palustris	Mugger crocodile	I	7/1/75
+ *C. porosus* (except populations of Australia, Papua New Guinea, and Indonesia).	Saltwater crocodile	I	7/1/75
+ *C. porosus* (Australia and Papua New Guinea populations)	Saltwater crocodile	II	7/1/75
+ *C. porosus* (Indonesian population subject to ranching provisions).	Saltwater crocodile	II	7/1/75

Species	Common name	Appendix	First listing date (month/day/year)
C. rhombifer	Cuban crocodile	I	7/1/75
C. siamensis	Siamese crocodile	I	7/1/75
Gavialis gangeticus	Gavial, Gharial	I	7/1/75
Melanosuchus niger (except for population of Ecuador)	Black caiman	I	7/1/75
+ M. niger (population of Ecuador, subject to zero export quotas in 1995 and 1996, followed by annual quotas described by the Secretariat).	Black caiman	II	7/1/75
Osteolaemus tetraspis (except subspecies listed below)	Dwarf crocodile	I	2/4/77
O. tetraspis osborni	Dwarf crocodile	I	7/1/75
O. tetraspis tetraspis	Dwarf crocodile	I	7/1/75
Paleosuchus trigonatus	Smooth-fronted caiman	II	7/1/75
Tomistoma schlegelii	Tomistoma, False gavial	I	7/1/75
Order Rhynchocephalia:	Tuatara:		
+ Sphenodon spp.	Tuataras	I	7/1/75
Order Sauria:	Lizards:		
Amblyrhynchus cristatus	Galapagos marine iguana	II	7/1/75
Brachylophus spp.	Fiji iguanas	I	6/6/81
Bradypodion spp.	Chameleons	II	2/4/77
Chamaeleo spp.	Chamaeleons	II	2/4/77
Cnemidophorus hyperythrus	Orange-throated whiptail lizard	II	7/1/75
Conolophus spp. (except species listed below)	Land lizards	II	2/4/77
C. pallidus	Barrington Island land lizard	II	7/1/75
C. subcristatus	Galapagos land iguana	II	7/1/75
Cordylus spp.	Girdled lizards	II	6/6/81
Corucia zebrata	Prehensile-tailed skink	II	6/11/92
Crocodilurus lacertinus	Dragon lizardet	II	2/4/77
Cyclura spp.	Ground iguanas	I	2/4/77
Cyrtodactylus serpensinsula	Serpent Island gecko	II	2/4/77
Dracaena spp.	Caiman lizards	II	2/4/77
Gallotia simonyi	Hierro giant lizard	I	10/22/87
Heloderma spp.	Beaded lizards, Gila monster	II	7/1/75
Iguana spp.	Iguanas	II	2/4/77
Phelsuma spp.	Day geckos	II	2/4/77
Phrynosoma coronatum (except subspecies with earlier date in App. II).	Coastal horned lizards	II	6/11/92
P. coronatum blainvillei	San Diego horned lizard	II	7/1/75
Podarcis lilfordi	Lilford's wall lizard	II	10/22/87
P. pityusensis	Ibiza wall lizard	II	10/22/87
Pseudocordylus spp.	Crag lizards	II	6/6/81
Sauromalus varius	San Esteban Island chuckwalla	I	6/6/81
Shinisaurus crocodilurus	Chinese crocodile lizard	II	1/18/90
Tupinambis spp.	Tegu lizards	II	2/4/77
Uromastyx spp.	Spiny-tailed lizards	II	2/4/77
Varanus spp. (all species except those in App. I)	Monitor lizards	II	7/1/75
V. bengalensis	Indian monitor, Bengal monitor	I	7/1/75
V. flavescens	Yellow monitor	I	7/1/75
V. griseus	Desert monitor	I	7/1/75
V. komodoensis	Komodo Island monitor, Komodo dragon	I	7/1/75
Order Serpentes:	Snakes:		
Acrantophis spp.	Madagascar boas	I	2/4/77
Agkistrodon bilineatus	Cantil	III (Honduras)	4/13/87
Atretium schistosum	Olive keelback water snake	III (India)	2/12/84
Boa (=*Constrictor*) *constrictor*	Boa constrictor	II	7/1/75
Boa constrictor occidentalis	Argentine boa constrictor	I	2/4/77
Boidae spp. (all species except those in App. I or with earlier date in App. II).	Boa constrictors, Pythons	II	2/4/77
Bolyeria multocarinata	Round Island boa	I	2/4/77
Bothrops asper	Terciopelo	III (Honduras)	4/13/87
B. nasutus	Rainforest hognosed pit-viper	III (Honduras)	4/13/87
B. nummifer	Jumping pit-viper	III (Honduras)	4/13/87
B. ophryomegas	Slender hognosed pit-viper	III (Honduras)	4/13/87
B. schlegelii	Eyelash palm pit-viper	III (Honduras)	4/13/87
Casarea dussumieri	Round Island boa	I	2/4/77
Cerberus rhynchops	Dog-faced water snake	III (India)	2/12/84
Clelia (=*Pseudoboa*) *clelia*	Mussurana snake	II	7/1/75
Crotalus durissus	Tropical rattlesnake, Cascabel	III (Honduras)	4/13/87
Cyclagras (=*Hydrodynastes*) *gigas*	South American false water cobra	II	7/1/75
Elachistodon westermanni	Indian egg-eating snake	II	7/1/75
Epicrates cenchria cenchria	Rainbow boa	II	7/1/75
E. inornatus	Puerto Rican boa	I	2/4/77
E. monensis	Mona boa	I	2/4/77

Species	Common name	Appendix	First listing date (month/day/year)
E. subflavus	Jamaican boa	I	7/1/75
Eunectes notaeus	Yellow anaconda	II	7/1/75
Hoplocephalus bungaroides	Broad-headed snake	II	8/1/85
Micrurus diastema	Atlanta coral snake	III (Honduras)	4/13/87
M. nigrocinctus	Black-banded coral snake	III (Honduras)	4/13/87
Naja naja	Indian cobra	II	2/12/84
Ophiophagus hannah	King cobra	II	2/12/84
Ptyas mucosus	Oriental rat snake, Whipsnake	II	2/12/84
Python spp. (except subspecies listed below)	Pythons	II	7/1/75
P. molurus molurus	Indian python	I	7/1/75
Sanzinia madagascariensis	Tree boa	I	2/4/77
Vipera russellii	Russell's viper	III (India)	2/12/84
V. ursinii (except USSR populations)	Orsini's viper	I	10/22/87
V. wagneri	Wagner's viper	II	6/11/92
Xenochrophis (=*Natrix*) *piscator*	Checkered keelback water snake	III (India)	2/12/84
CLASS AMPHIBIA:	AMPHIBIANS:		
Order Caudata:	Salamanders:		
Ambystoma dumerilii	Lake Patzcuaro salamander	II	7/1/75
A. mexicanum	Axolotl	II	7/1/75
Andrias spp.	Giant salamanders	I	7/1/75
Order Anura:	Frogs, Toads:		
Atelopus varius zeteki	Panamanian golden frog	I	7/1/75
+ *Bufo periglenes*	Monte Verde golden toad	I	7/1/75
B. retiformis	Sonoran green toad	II	7/1/75
B. superciliaris	Cameroon toad	I	7/1/75
Dendrobates spp.	Poison dart frogs, Poison arrow frogs	II	10/22/87
Dyscophus antongilii	Tomato frog	I	10/22/87
Epipedobates spp. (see *Dendrobates* spp.)			
+ *Mantella aurantiaca*	Malagasy golden mantella	II	2/16/95
Minyobates spp. (see *Dendrobates* spp.)			
Nectophrynoides spp.	African viviparous toads	I	7/1/75
Phyllobates spp.	Poison arrow frogs	II	10/22/87
Rana hexadactyla	Asian bullfrog	II	8/1/85
R. tigerina	Indian bullfrog	II	8/1/85
Rheobatrachus spp.	Platypus frog	II	8/1/85
CLASS OSTEICHTHYES:	BONY FISHES:		
Order Ceratodontiformes (=Ceratodiformes):	Lungfishes:		
Neoceratodus forsteri	Australian lungfish	II	7/1/75
Order Coelacanthiformes:	Coelacanth:		
Latimeria chalumnae	Coelacanth, Gombessa	I	7/1/75
Order Acipenseriformes:	Sturgeons:		
Acipenser brevirostrum	Short-nosed sturgeon	I	7/1/75
A. oxyrhynchus	Atlantic sturgeon	II	7/1/75
A. sturio	Baltic sturgeon	I	7/1/75
Polyodon spathula	Paddlefish	II	6/11/92
Order Osteoglossiformes:	Bonytongues:		
Arapaima gigas	Arapaima	II	7/1/75
+ *Scleropages formosus*	Asian bonytongue	I	7/1/75
Order Cypriniformes:			
Caecobarbus geertsi	African blind barb, Congo blind barb	II	6/6/81
Chasmistes cujus	Cui-ui	I	7/1/75
Probarbus jullieni	Ikan temolek, Pla eesok	I	7/1/75
Order Siluriformes:	Catfishes:		
Pangasianodon gigas	Thailand giant catfish	I	7/1/75
Order Perciformes:	Perch-like fishes:		
Cynoscion macdonaldi	Totoaba	I	2/4/77
PHYLUM ARTHROPODA:	ARTHROPODS:		
CLASS Insecta:	Insects:		
Bhutanitis spp.	Bhutan glory swallowtails	II	10/22/87
Ornithoptera spp. (all species except those in App. I or with earlier date in App. II).	Birdwing butterflies	II	2/16/79
O. alexandrae	Queen Alexandra's birdwing butterfly	I	2/4/77
O. allotei	Birdwing butterfly	II	2/4/77
O. chimaera	Birdwing butterfly	II	2/4/77
O. goliath	Birdwing butterfly	II	2/4/77
O. meridionalis	Birdwing butterfly	II	2/4/77
O. paradisea	Paradise birdwing butterfly	II	2/4/77
O. victoriae	Queen Victoria's birdwing butterfly	II	2/4/77
Papilio chikae	Luzon peacock swallowtail	I	10/22/87
P. homerus	Homerus swallowtail	I	10/22/87
P. hospiton	Corsican swallowtail	I	10/22/87

Species	Common name	Appendix	First listing date (month/day/year)
Parnassius apollo	Mountain apollo butterfly	II	2/4/77
P. apollo apollo	Mountain apollo butterfly	II	7/1/75
Teinopalpus spp.	Kaiser-I-Hind butterflies	II	10/22/87
Trogonoptera spp.	Birdwing butterflies	II	2/16/79
Troides spp.	Birdwing butterflies	II	2/16/79
CLASS Arachnida:	Arachnids:		
+ *Brachypelma* (=*Euathlus*) spp. (except species with earlier date in App. II).	Red-kneed tarantulas	II	2/16/95
B. smithi	Red-kneed tarantula	II	8/1/85
+ *Pandinus dictator*	Emperor scorpion	II	2/16/95
+ *P. gambiensis*	Emperor scorpion	II	2/16/95
+ *P. imperator*	Emperor scorpion	II	2/16/95
PHYLUM ANNELIDA:	ANNELID WORMS:		
CLASS Hirudinea:	Leeches:		
Order Arhynchobdelliformes:	Rhynchobedellids:		
Hirudo medicinalis	Medicinal leech	II	10/22/87
PHYLUM MOLLUSCA:	MOLLUSCS:		
CLASS Pelecypoda (=*Bivalvia):*	Clams, Mussels:		
Conradilla caelata	Birdwing pearly mussel	I	7/1/75
Cyprogenia aberti	Edible pearly mussel	II	7/1/75
Dromus dromas	Dromedary pearly mussel	I	7/1/75
Epioblasma (=*Dysnomia*) *curtisi* (=*E. florentina curtisi*)	Curtis' pearly mussel	I	7/1/75
E. florentina (=*E. florentina florentina*)	Yellow-blossom pearly mussel	I	7/1/75
E. sampsoni	Sampson's pearly mussel	I	7/1/75
E. sulcata perobliqua	White cat's paw mussel	I	7/1/75
E. torulosa gubernaculum	Green-blossom pearly mussel	I	7/1/75
E. torulosa rangiana	Tan-blossom pearly mussel	II	7/1/75
E. torulosa torulosa	Tuberculed-blossom pearly mussel	I	7/1/75
E. turgidula	Turgid-blossom pearly mussel	I	7/1/75
E. walkeri	Brown-blossom pearly mussel	I	7/1/75
Fusconaia cuneolus	Fine-rayed pigtoe mussel	I	7/1/75
F. edgariana	Shiny pigtoe mussel	I	7/1/75
F. subrotunda	Long solid mussel	II	7/1/75
Hippopus spp. (see Tridacnidae spp.)			
Lampsilis brevicula	Ozark lamp pearly mussel	II	7/1/75
L. higginsii	Higgin's eye mussel	I	7/1/75
L. orbiculata orbiculata	Pink mucket mussel	I	7/1/75
L. satur	Plain pocketbook mussel	I	7/1/75
L. virescens	Alabama lamp pearly mussel	I	7/1/75
Lexingtonia dolabelloides	Slab-side pearly mussel	II	7/1/75
Plethobasus cicatricosus	White wartyback mussel	I	7/1/75
P. cooperianus	Orange-footed pimpleback mussel	I	7/1/75
Pleurobema clava	Club pearly mussel	II	7/1/75
P. plenum	Rough pigtoe mussel	I	7/1/75
Potamilus (=*Proptera*) *capax*	Fat pocketbook mussel	I	7/1/75
Quadrula intermedia	Cumberland monkey-face mussel	I	7/1/75
Q. sparsa	Appalachian monkey-face mussel	I	7/1/75
Toxolasma (=*Carunculina*) *cylindrella*	Pale lilliput pearly mussel	I	7/1/75
Tridacna derasa	Giant clam	II	5/29/83
T. gigas	Giant clam	II	5/29/83
Tridacnidae spp. (includes all species in genera *Hippopus* and *Tridacna* except those with earlier date in App. II).	Giant clams	II	8/1/85
Unio (=*Megalonaias*) *nickliniana*	Nicklin's pearly mussel	I	7/1/75
U. (=*Lampsilis* or *Cyrtonaias*) *tampicoensis tecomatensis*	Tampico pearly mussel	I	7/1/75
Villosa (=*Micromya*) *trabalis*	Cumberland bean mussel	I	7/1/75
CLASS Gastropoda:	Snails:		
Achatinella spp.	Oahu tree snails	I	10/22/87
Papustyla (=*Papuina*) *pulcherrima*	Manus Island tree snail	II	7/1/75
Paryphanta spp. (New Zealand species only)	New Zealand amber snails	II	7/1/75
Strombus gigas	Queen conch	II	6/11/92
PHYLUM CNIDARIA (=COELENTERATA):	CORAL-LIKE ANIMALS:		
CLASS Anthozoa:	Corals, Sea anemones:		
Order Coenothecalia:			
All species in the Order (except those in genus with earlier date).		II	1/18/90
Heliopora spp.	Blue corals	II	8/1/85
Order Stolonifera:			
Tubiporidae spp. (all species in family except genus with earlier date).		II	1/18/90
Tubipora spp.	Organ-pipe corals	II	8/1/85
Order Antipatharia:	Black corals:		
All species in the Order		II	6/6/81

Species	Common name	Appendix	First listing date (month/day/year)
Order Scleractinia:	Stony corals:		
All species in the Order (except the following genera with earlier date).		II	1/18/90
Acropora spp.	Staghorn corals	II	8/1/85
Euphyllia spp.	Trumpet corals	II	8/1/85
Favia spp.	Brain corals	II	8/1/85
Fungia spp.	Mushroom corals	II	8/1/85
Halomitra spp.	Bowl corals	II	8/1/85
Lobophyllia spp.	Brain corals	II	8/1/85
Merulina spp.	Merulinas	II	8/1/85
Pavona spp.	Cactus corals	II	8/1/85
Pectinia spp.	Lettuce corals	II	8/1/85
Platygyra spp.	Brain corals	II	8/1/85
Pocillopora spp.	Brush corals	II	8/1/85
Polyphyllia spp.	Feather corals	II	8/1/85
Seriatopora spp.	Birds nest corals	II	8/1/85
Stylophora spp.	Cauliflower corals	II	8/1/85
CLASS Hydrozoa:	Sea ferns, Fire corals, Stinging medusae:		
Order Milleporina (=Athecata):			
Milleporidae spp. (all species in family except genus with earlier date).		II	1/18/90
Millepora spp.	Fire corals	II	8/1/85
Order Stylasterina:			
Stylasteridae spp. (all species in family).		II	1/18/90
PLANT KINGDOM:	PLANTS:		
Family Agavaceae:	Agave family:		
Agave arizonica	New River agave	I	7/29/83
A. parviflora	Santa Cruz striped agave	I	7/29/83
A. victoriae-reginae	Queen Victoria agave	II	7/29/83
Nolina interrata	Dehesa bear-grass	I	7/29/83
Family Amaryllidaceae:	Amaryllis family:		
Galanthus spp. (and their natural hybrids)	Snowdrops	II	1/18/90
Sternbergia spp.	Sternbergias	II	1/18/90
Family Apocynaceae:	Dogbane family:		
Pachypodium spp. (except species listed in App. I)	Pachypodiums	II	7/1/75
+ *P. ambongense* (and its natural hybrids)		I	7/1/75
P. baronii (and its natural hybrids)		I	7/1/75
+ *P. brevicaule* (and its natural hybrids; no exports of adult plants before tenth Conference of the Parties, ca. March, 1997).		II	7/1/75
P. decaryi (and its natural hybrids)		I	7/1/75
Rauvolfia serpentina (except chemical derivatives)	Snake-root devil-pepper	II	1/18/90
Family Araliaceae:	Ginseng family:		
Panax quinquefolius	American ginseng	II	7/1/75
Family Araucariaceae:	Monkey-puzzle tree family:		
Araucaria araucana (all populations except that of Chile)	Monkey-puzzle tree	II	7/1/75
A. araucana (population of Chile)	Monkey-puzzle tree	I	7/1/75
Family Asclepiadaceae:	Milkweed family:		
Ceropegia spp.	Ceropegias	II	6/28/79
Frerea indica		II	6/28/79
Family Berberidaceae:	Barberry family:		
Podophyllum hexandrum (=*P. emodi*, =*Sinopodophyllum hexandrum*) (except chemical derivatives).	Himalayan may-apple	II	1/18/90
Family Bromeliaceae:	Pineapple family:		
Tillandsia harrisii	Harris tillandsia	II	6/11/92
T. kammii	Kamm tillandsia	II	6/11/92
T. kautskyi	Kautsky tillandsia	II	6/11/92
T. mauryana	Maury tillandsia	II	6/11/92
T. sprengeliana	Sprengel tillandsia	II	6/11/92
T. sucrei	Sucre tillandsia	II	6/11/92
T. xerographica	Xerographic tillandsia	II	6/11/92
Family Byblidaceae:	Byblis family:		
Byblis spp.	Byblis, Rainbow plants	II	6/28/79
Family Cactaceae:	Cactus family:		
All species except those in App. I	Cacti	II	7/1/75
Ariocarpus spp. (includes *Neogomesia* sp. and *Roseocactus* spp.).	Living-rock cacti	I	7/1/75
Astrophytum (=*Echinocactus*) *asterias*	Sea-urchin cactus, Star cactus	I	7/1/75
Aztekium ritteri	Aztec cactus	I	7/1/75
Coryphantha (other than *C. werdermannii*) (see *Escobaria*) ..			
C. werdermannii	Jabali pincushion cactus	I	7/1/75

Species	Common name	Appendix	First listing date (month/day/year)
Discocactus spp.	Discocacti	I	7/1/75
Disocactus (=*Lobeira*, =*Nopalxochia*) *macdougallii*	MacDougall's cactus	I	7/1/75
Echinocereus ferreirianus var. *lindsayi* (=*E. lindsayi*)	Lindsay's hedgehog cactus	I	7/1/75
E. (=*Wilcoxia*) *schmollii*	Lamb's-tail cactus	I	7/1/75
Escobaria leei (=*E. sneedii* var. *leei*)	Lee pincushion cactus	I	7/1/75
E. minima	Nellie's corycactus	I	7/1/75
E. sneedii	Sneed pincushion cactus	I	7/1/75
Mammillaria pectinifera (=*Solisia pectinata*)	Conchilinque	I	7/1/75
M. solisioides	Pitayita	I	7/1/75
Melocactus conoideus	Conelike Turk's-cap cactus	I	7/1/75
M. deinacanthus	Wonderfully bristled Turk's-cap cactus	I	7/1/75
M. glaucescens	Wooly waxy-stemmed Turk's-cap cactus	I	7/1/75
M. paucispinus	Few-spined Turk's-cap cactus	I	7/1/75
Obregonia denegrii	Artichoke cactus	I	7/1/75
Pachycereus (=*Backebergia*) *militaris*	Teddy-bear cactus, Military cap	I	7/1/75
Pediocactus (=*Toumeya*) *bradyi*	Brady's pincushion cactus	I	7/1/75
P. despainii	San Rafael cactus	I	7/1/75
P. (=*Toumeya*) *knowltonii*	Knowlton's cactus	I	7/1/75
P. (=*Toumeya*) *papyracanthus* (see *Sclerocactus papyracanthus*).			
P. paradinei	Houserock Valley cactus	I	7/1/75
P. peeblesianus (=*Toumeya fickeisenii*, =*T. peeblesiana*)	Peebles' Navajo cactus	I	7/1/75
P. sileri	Siler's pincushion cactus	I	7/1/75
P. winkleri	Winkler's cactus	I	7/1/75
Pelecyphora spp. (includes *Encephalocarpus* sp.)	Hatchet cactus, Pinecone cactus, Peyotillo	I	7/1/75
Sclerocactus brevihamatus subsp. *tobuschii* (=*Ancistrocactus tobuschii*, =*Echinocactus tobuschii*).	Tobusch fishhook cactus	I	7/1/75
S. (=*Echinomastus, =Neolloydia*) *erectocentrus*		I	7/1/75
S. glaucus	Uinta Basin hookless cactus	I	7/1/75
S. (=*Echinomastus*, =*Neolloydia*) *mariposensis*	Mariposa cactus	I	7/1/75
S. mesae-verdae	Mesa Verde cactus	I	7/1/75
S. papyracanthus	Grama-grass cactus	I	7/1/75
S. pubispinus	Great Basin fishhook cactus	I	7/1/75
S. wrightiae	Wright's fishhook cactus	I	7/1/75
Strombocactus disciformis	Disc cactus, Top cactus	I	7/1/75
Turbinicarpus spp. (includes *Gymnocactus* spp., most *Neolloydia* spp. (in sense of E.F. Anderson 1986), *Normanbokea* spp., and *Rapicactus* spp.).	Turbinicarps	I	7/1/75
Uebelmannia spp.	Uebelmann cacti	I	7/1/75
Family Caryocaraceae:	Souari family:		
Caryocar costaricense	Ajo	II	7/1/75
Family Cephalotaceae:	Australian pitcher-plant family:		
Cephalotus follicularis	West Australian pitcher plant	II	6/28/79
Family Compositae (=Asteraceae):	Aster family:		
Saussurea costus (=*lappa*)	Costus, Kuth root	I	7/1/75
Family Crassulaceae:	Stonecrop family:		
Dudleya stolonifera	Laguna Beach dudleya	I	7/29/83
D. traskiae	Santa Barbara Island dudleya	I	7/29/83
Family Cupressaceae:	Cypress family:		
Fitz-Roya cupressoides	Fitzroya, Alerce	I	7/1/75
Pilgerodendron uviferum	Pilgerodendron	I	7/1/75
Family Cyatheaceae:	Tree-fern family:		
All species in the family except those with earlier date		II	2/4/77
Cyathea (=*Hemitelia*) *capensis*		II	7/1/75
C. dredgei		II	7/1/75
C. mexicana		II	7/1/75
C. (=*Alsophila*) *salvinii*		II	7/1/75
Family Cycadaceae:	Cycas family:		
All species in the family except species in App. I		II	2/4/77
Cycas beddomei	Beddome cycad	I	2/4/77
Family Diapensiaceae:	Diapensia family:		
Shortia galacifolia	Oconee bells	II	7/29/83
Family Dicksoniaceae:	Tree-fern family:		
All species in the family		II	2/4/77
Family Didiereaceae:	Alluaudia family:		
All species in the family		II	2/4/77
Family Dioscoreaceae:	Yam family:		
Dioscorea deltoidea	Kniss, Kurta	II	7/1/75
Family Droseraceae:	Sundew family:		
Dionaea muscipula	Venus flytrap	II	6/11/92
Family Ericaceae:	Heath family:		
Kalmia cuneata	White wicky	II	7/29/83

Species	Common name	Appendix	First listing date (month/day/year)
Family Euphorbiaceae:	Spurge family:		
Euphorbia spp. (excluding non-succulent species) (all species except those in App. I).	Euphorbias	II	7/1/75
E. subgenus *Lacanthis* dwarf species in Madagascar and their natural hybrids as given below:	Malagasy dwarf euphorbias as shown:		
E. ambovombensis (and its natural hybrids)		I	7/1/75
+ *E. cremersii*		I	7/1/75
E. cylindrifolia (including subsp. *tuberifera*) (and its natural hybrids).		I	7/1/75
E. decaryi (including var. *capsaintemariensis*, *E. capsaintemariensis*) (and its natural hybrids).		I	7/1/75
E. francoisii (and its natural hybrids)		I	7/1/75
E. moratii (and its natural hybrids)		I	7/1/75
E. parvicyathophora (and its natural hybrids)		I	7/1/75
E. quartziticola (and its natural hybrids)		I	7/1/75
E. tulearensis (= *E. capsaintemariensis* var. *tulearensis*) (and its natural hybrids).		I	7/1/75
Family Fouquieriaceae:	Ocotillo family:		
Fouquieria columnaris	Boojum tree	II	7/29/83
F. fasciculata	Arbol del barril	I	7/29/83
F. purpusii		I	7/29/83
Family Gnetaceae:	Gnetum family:		
Gnetum montanum		III (Nepal)	11/16/75
Family Juglandaceae:	Walnut family:		
Oreomunnea (=*Engelhardia*) *pterocarpa*	Gavilán	II	7/1/75
Family Leguminosae (=Fabaceae):	Pea family:		
Dalbergia nigra	Brazilian rosewood	I	6/11/92
Pericopsis elata (including saw-logs, sawn wood, and veneers, but no other parts or derivatives, i.e., products).	Afrormosia	II	6/11/92
Platymiscium pleiostachyum	Cristobal, Granadillo	II	7/1/75
+ *Pterocarpus santalinus* (only logs, wood-chips, and unprocessed broken material).	Red sandalwood, Redsanders	II	2/16/95
Family Liliaceae:	Lily family:		
Aloe spp. (all except those in App. I, and excluding *A. vera* [=*barbadensis*] except *A. vera* var. *chinensis*).	Aloes	II	7/1/75
A. albida		I	7/1/75
+ *A. albiflora*		I	7/1/75
+ *A. alfredii*		I	7/1/75
+ *A. bakeri*		I	7/1/75
+ *A. bellatula*		I	7/1/75
+ *A. calcairophila*		I	7/1/75
+ *A. compressa* (incl. var. *rugosquamosa*, var. *schistophila*)		I	7/1/75
+ *A. delphinensis*		I	7/1/75
+ *A. descoingsii*		I	7/1/75
+ *A. fragilis*		I	7/1/75
+ *A. haworthioides* (incl. var. *aurantiaca*)		I	7/1/75
+ *A. helenae*		I	7/1/75
+ *A. laeta* (incl. var. *maniensis*)		I	7/1/75
+ *A. parallelifolia*		I	7/1/75
+ *A. parvula*		I	7/1/75
A. pillansii	Boomaalwyn	I	7/1/75
A. polyphylla	Spiral aloe	I	7/1/75
+ *A. rauhii*		I	7/1/75
+ *A. suzannae*		I	7/1/75
A. thorncroftii		I	7/1/75
+ *A. versicolor*		I	7/1/75
A. vossii		I	7/1/75
Family Magnoliaceae:	Magnolia family:		
Talauma hodgsonii		III (Nepal)	11/16/75
Family Meliaceae:	Mahogany family:		
Swietenia humilis	Pacific Coast mahogany	II	7/1/75
S. mahagoni (including saw-logs, sawn wood, and veneers, but no other parts or derivatives, i.e., products).	Caribbean mahogany	II	6/11/92
Family Nepenthaceae:	Old World pitcher-plant family:		
Nepenthes spp. (all species except those in App. I)	Tropical pitcher plants	II	10/22/87
N. khasiana	Indian tropical pitcher plant	I	10/22/87
N. rajah	Giant tropical pitcher plant	I	6/6/81
Family Orchidaceae (= Apostasiaceae, Cypripediaceae):	Orchid family:		
All species except those in App. I	Orchids	II	7/1/75
Cattleya trianae	Christmas orchid	I	7/1/75
+ *Dendrobium cruentum*		I	7/1/75

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Laelia jongheana		I	7/1/75
L. lobata		I	7/1/75
Paphiopedilum spp.	Asian tropical lady's slippers	I	7/1/75
Peristeria elata	Holy Ghost, Dove orchid	I	7/1/75
Phragmipedium spp. (includes *Mexipedium* sp.)	New World tropical lady's slippers	I	7/1/75
Renanthera imschootiana		I	7/1/75
Vanda coerulea	Blue vanda	I	7/1/75
Family Palmae (=Arecaceae):	Palm family:		
Chrysalidocarpus decipiens		II	2/4/77
Neodypsis decaryi	Triangle palm	II	7/1/75
Family Papaveraceae:	Poppy family:		
Meconopsis regia		III (Nepal)	11/16/75
Family Pinaceae:	Pine family:		
Abies guatemalensis	Guatemalan fir	I	7/1/75
Family Podocarpaceae:	Podocarp family:		
Podocarpus neriifolius		III (Nepal)	11/16/75
P. parlatorei	Parlatore's podocarp, Monteromero	I	7/1/75
Family Podophyllaceae (see Berberidaceae)			
Family Portulacaceae:	Portulaca family:		
Anacampseros spp.		II	7/1/75
Lewisia cotyledon	Siskiyou lewisia	II	7/29/83
L. maguirei	Maguire's lewisia	II	7/29/83
L. serrata	Saw-toothed lewisia	II	7/29/83
L. tweedyi	Tweedy's lewisia	II	7/29/83
Family Primulaceae:	Primrose family:		
Cyclamen spp.	Cyclamens	II	7/1/75
Family Proteaceae:	Protea family:		
Orothamnus zeyheri	Marsh-rose	I	7/1/75
Protea odorata	Ground-rose	I	7/1/75
Family Rosaceae:	Rose family:		
+ Prunus africana	African cherry	II	2/16/95
Family Rubiaceae:	Coffee family:		
Balmea stormiae	Ayuque	I	7/1/75
Family Sarraceniaceae:	New World pitcher-plant family:		
Darlingtonia californica	Western pitcher plant, Cobra-lily	II	6/6/81
Sarracenia spp. (all species and natural hybrids except species in App. I).	Trumpet pitcher plants	II	10/22/87
S. alabamensis subsp. *alabamensis* (=*S. rubra* subsp. *alabamensis*).	Alabama canebrake pitcher plant	I	6/6/81
S. jonesii (=*S. rubra* subsp. *jonesii*)	Mountain sweet pitcher plant	I	6/6/81
S. oreophila	Green pitcher plant	I	6/6/81
Family Stangeriaceae:	Stangeria family:		
Stangeria eriopus (=*paradoxa*)	Stangeria, Fern-leafed cycad	I	7/1/75
Family Taxaceae:	Yew family:		
+ Taxus wallichiana (=*T. baccata* subsp. *wallichiana*) (except finished pharmaceutical products).	Himalayan yew	II	2/16/95
Family Tetracentraceae:	Tetracentron family:		
Tetracentron sinense	Tetracentron	III (Nepal)	11/16/75
Family Theaceae:	Tea family:		
Camellia chrysantha	Yellow-flowered camellia, Jinhuacha	II	8/1/85
Family Thymelaeaceae (=Aquilariaceae):	Mezereon family:		
+ Aquilaria malaccensis	Agarwood, Aloewood	II	2/16/95
Family Welwitschiaceae:	Welwitschia family:		
Welwitschia mirabilis (=*bainesii*)	Welwitschia	II	7/1/75
Family Zamiaceae:	Cycad family:		
All species except those in App. I		II	2/4/77
Ceratozamia spp.	Ceratozamias, Horncones	I	2/4/77
Chigua spp.		I	2/4/77
Encephalartos spp.	Bread palms, African cycads	I	7/1/75
Microcycas calocoma	Palma corcho, Microcycas	I	7/1/75
Family Zingiberaceae:	Ginger family:		
Hedychium philippinense	Philippine garland flower	II	7/1/75
Family Zygophyllaceae:	Cresote-bush family:		
Guaiacum officinale	Commoner lignum vitae	II	6/11/92
G. sanctum	Holywood lignum vitae	II	7/1/75

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 310 et al.

Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 355, and 369

[Docket No. 80N–0042]

RIN 0910–AA01

Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) anticaries drug products (products that aid in the prevention of dental cavities) are generally recognized as safe and effective and not misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on OTC anticaries drug products that have come to the agency's attention. This final monograph is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 28, 1980 (45 FR 20666), 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 anticaries drug products, together with the recommendations of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by June 26, 1980. Reply comments in response to comments filed in the initial comment period could be submitted by July 28, 1980.

In accordance with § 330.10(a)(10), the data and information considered by the Panel, after deletion of a small amount of trade secret information, were placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC anticaries drug products was published in two segments. The first segment was published in the Federal Register of September 30, 1985 (50 FR 39854). It addressed general issues on OTC anticaries drug products, the switch of prescription anticaries drug products to OTC status, specific anticaries active ingredients, dosages for anticaries active ingredients, and labeling of anticaries drug products. Interested persons were invited to file by November 29, 1985, written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs (the Commissioner). Interested persons were invited to file comments on the agency's economic impact determination by January 28, 1986. New data could have been submitted until September 30, 1986, and comments on the new data until December 1, 1986.

The agency stated in the advance notice of proposed rulemaking that the Panel's recommended Laboratory Testing Profiles (LTP's) represented a new concept with many technical issues yet to be resolved. Thus, the LTP's were not included in the first segment of the tentative final monograph. The agency mentioned in the tentative final monograph (50 FR 39854) that an open public meeting was held on September 26 and 27, 1983, to discuss unresolved technical issues concerning the LTP's. The LTP's were subsequently discussed in the second segment of the tentative final monograph, published in the Federal Register of June 15, 1988 (53 FR 22430). This amendment of the tentative final monograph addressed final formulation testing for monograph active ingredients in dentifrice formulations and issues relating to this testing. Interested persons were invited to file by October 13, 1988, written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner. Interested persons were invited to file comments on the agency's economic impact determination by October 13, 1988. New data could have been submitted until June 15, 1989, and comments on the new data until August 15, 1989.

In a notice published in the Federal Register of May 8, 1992 (57 FR 19823), the agency reopened the administrative record to include data and information in support of a request to increase the package size limitation for fluoride dentifrice drug products from not more than 260 milligrams (mg) of total fluorine per package to not more than 350 mg. Interested persons were invited to submit written comments by July 7, 1992.

In the Federal Register of November 24, 1992 (57 FR 55199), the agency also reopened the administrative record to obtain public comment on whether the labeling of OTC fluoride-containing drug products should include the quantity of fluoride, i.e., the specific amount of fluoride present in the product. Interested persons were invited to submit written comments by January 25, 1993. In the Federal Register of January 26, 1993 (58 FR 6102), the agency extended the comment period to March 26, 1993.

This final rule encompasses all of the above segments. Final agency action on all OTC anticaries drug products occurs with the publication of this final rule establishing a monograph for OTC anticaries drug products.

The OTC drug procedural regulations (§ 330.10) 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 is no longer using 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. In place of Category I, the term ''monograph conditions'' is used; in place of Category II or III, the term ''nonmonograph conditions'' is used.

As discussed in the proposed regulation for OTC anticaries drug products (50 FR 39854), the agency advised that the conditions under which the drug products that are subject to this monograph will be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication in the Federal Register. Therefore, on or after October 7, 1996, 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 or abbreviated application (hereinafter called 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 response to the proposed rule, the amended proposed rule, and the two reopenings of the administrative record for OTC anticaries drug products, 19 drug manufacturers, 2 drug manufacturers associations, 2 health care professionals, 1 health care professional society, and 3 academic institutions submitted comments. Copies of the comments are on public display in the Dockets Management Branch (address above.) Additional information that has come to the agency's attention since the publication of the proposed rule, amended proposed rule, and notices to reopen the administrative record is also on display in the Dockets Management Branch.

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.

I. The Agency's Conclusions on the Comments

A. General Comments on Anticaries Drug Products

1. One comment noted its continuing position that FDA could not legally and should not, as a matter of policy, prescribe exclusive lists of terms from which indications for use for OTC drug products must be drawn.The comment stated that FDA could not legally prohibit alternative OTC indications for use in terminology that is otherwise truthful and not misleading. The comment added that its views on this subject were presented in oral and written testimony submitted to FDA in connection with the September 29, 1982, FDA hearing on the exclusivity policy. The comment noted that a proposed revision to the exclusivity policy had been published on April 22, 1985 (50 FR 15810). The comment mentioned that it had submitted its views in response to that proposal and was incorporating those views into the rulemaking for OTC anticaries drug products. A second comment strongly supported the proposed revision of the exclusivity policy and discussed a number of constitutional and policy concerns about the agency's labeling policies for OTC drug products.

The agency notes that the comments in the current rulemaking were submitted before the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products in the Federal Register of May 1, 1986 (51 FR 16258). The comments' concerns were addressed by the agency's change in its labeling policy for stating indications for use. Under the new policy in § 330.1(c)(2) (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.

2. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

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 at 9467 to 9472); in paragraph 3 of the preamble to the tentative final monograph for OTC antacid drug products, published in the Federal Register of November 12, 1973 (38 FR 31260); and in paragraph 1 of the preamble to the tentative final monograph in the present proceeding (50 FR 39854 at 39855). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by informal rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696–698 (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 noted that interested persons must file new data within 1 year after publication of a tentative final monograph per 21 CFR 330.10(a)(7)(iii). For this reason, the comment contended that it is important that persons submitting comments or objections to the tentative final monograph be provided with early feedback from FDA so that sufficient time will remain to allow any necessary additional testing or market research. The comment requested that the agency provide feedback on requests no later than 6 months following the submission of comments or objections to the proposed rule. The comment also asked that the agency's regulations for the OTC drug review be amended to contain this provision.

The agency is unable to make a specific commitment to provide feedback on all comments and objections received in this and other OTC drug rulemakings within a specific time frame, as requested by the comment. Competing priorities and the constraints of limited resources make this impossible to do. However, the agency does review all comments and objections and tries to provide timely feedback as the situation requires and as workloads permit.

4. The Public Health Service Ad Hoc Subcommittee on Fluoride of the Committee to Coordinate Environmental Health and Related Programs (the Subcommittee) discussed dental fluorosis resulting from fluoride intake in its report entitled ''Review of Fluoride: Benefits and Risks'' (Ref. 1). The Subcommittee stated that dental fluorosis only occurs during tooth formation and becomes apparent upon eruption of the teeth. Dental fluorosis ranges from very mild (symmetrical whitish areas on teeth) to severe (pitting of the enamel, frequently associated with brownish discoloration). The Subcommittee recommended that manufacturers of dental products explore whether the levels of fluoride in their products can be reduced while preserving clinical effectiveness. (However, the Subcommittee did not suggest an acceptable fluoride exposure level.) In response to the Subcommittee's recommendation, the agency asked a professional dental association and two manufacturers associations (Refs. 2, 3, and 4) for information on dentifrices containing low levels of fluoride, particularly for use by children 2 to under 6 years of age.

The dental association stated that it is not currently considering a low fluoride toothpaste, but would evaluate such a product if one were to be submitted.

The association indicated that such a product would be accepted if clinical data demonstrating effectiveness were available.

The two manufacturers associations provided a joint response, in which they reviewed the report and relevant clinical and epidemiological literature, with the following conclusions: (1) There is a lack of scientific support for a cause and effect relationship between the ingestion of fluoride from dentifrice products and the subsequent development of enamel fluorosis; (2) the reported increase in enamel fluorosis, which ranges from very mild to mild, appears to be a result of factors other than dentifrice use, while, importantly, dentifrice use has been the principal contributor to the caries decline over the past 20 years; and (3) manufacturing changes to reduce the fluoride content of baby formulas, as well as cautionary advice to physicians about the administration of fluoride supplements to young children, are steps that have already been initiated and may well counteract the increase of the very mild to mild forms of enamel fluorosis that have been reported, as new epidemiologic data become available in the future.

The manufacturers associations recommended that there be no reduction in the 850- to 1,150-parts per million (ppm) theoretical total fluorine levels proposed in the tentative final monograph for OTC anticaries drug products, contending that any reduction in this range could have serious public health consequences in terms of reducing the current level of anticaries protection in young children. The associations noted that data from studies evaluating low-potency (250 to 550 ppm) fluoride dentifrices were contradictory and very sparse in children 2 to 6 years of age.

The agency agrees that there is not enough evidence available at this time to support the safety and effectiveness of a low-fluoride dentifrice for children 2 to under 6 years of age, or to determine an appropriate fluoride concentration for a low-level dentifrice. As noted by the Subcommittee, dental fluorosis does not compromise oral health or tooth function as do dental caries. Therefore, the risk of dental caries from inadequate fluoride protection is a greater health hazard than the cosmetic detriment of fluorosis. Until adequate data become available, the agency is not able to generally recognize a low-fluoride dentifrice as safe and effective. If data become available, the agency will consider them.

References

(1) Department of Health and Human Services, ''Review of Fluoride Benefits and Risks: Report of the Ad Hoc Subcommittee on Fluoride, of the Committee to Coordinate Environmental Health and Related Programs,'' February, 1991, in OTC Vol. No. 08AFM, Docket No. 80N–0042, Dockets Management Branch.

(2) Comment No. LET15, Docket No. 80N–0042, Dockets Management Branch.

(3) Comment No. LET16, Docket No. 80N–0042, Dockets Management Branch.

(4) Comment No. LET17, Docket No. 80N–0042, Dockets Management Branch.

5. One comment stated that the proposed definitions for dentifrice, treatment gel, and treatment rinse in § 355.3(d), (g), and (h), respectively, should be revised to exclude discussion of the ''cosmetic function or nonfunction'' of these treatment categories. The comment noted, for example, that the first sentence in the definition for dentifrice, ''A substance used with a toothbrush to clean the accessible surfaces of the teeth,'' refers to a cosmetic function and should be deleted. The comment proposed modifying the definitions for dentifrice and treatment gel to be consistent with the definition for a treatment rinse as follows: A dentifrice is an abrasive-containing dosage form for delivering an anticaries drug to the teeth, a treatment gel is a gel dosage form for delivering an anticaries drug to the teeth, and a treatment rinse is a liquid dosage form for delivering an anticaries drug to the teeth. The comment suggested the following alternative definition for the entire category of anticaries drug products rather than defining individual dosage forms: ''an anticaries drug product is one which aids in the prevention or treatment of dental caries. It may be formulated as an abrasive-containing paste or powder, nonabrasive-containing gel, liquid rinse, or other appropriate product types.'' The comment concluded that this alternative definition more clearly emphasizes the intended use of these products rather than emphasizing the dosage form.

Another comment requested that some proposed definitions of OTC anticaries dosage forms be revised to delete those terms that refer to both therapeutic and cosmetic functions. The comment specifically referred to the definitions in § 355.3(a) (abrasive), (d) (dentifrice), (g) (treatment gel), (h) (treatment rinse), (i) (treatment rinse concentrated solution), (j) (treatment rinse effervescent tablets), and (k) (treatment rinse powder). The comment contended that the combination of therapeutic and cosmetic functions in these definitions would be confusing and inappropriate. The comment recommended that this section be revised to more clearly emphasize the intended therapeutic function of these dosage forms. For example, ''an anticaries drug product is one which aids in the prevention or treatment of dental caries (decay, cavities) and may be formulated as an abrasive-containing dentifrice, paste, or powder, nonabrasive gel, liquid rinse, or effervescent powder or tablets.''

The agency has reviewed the Panel's evaluation of the definition of different fluoride dosage forms and concludes that there is a significant difference between dentifrices and nonabrasive dental gels and rinses. A dentifrice formulation contains an abrasive that is included in the formulation to clean the teeth (45 FR 20666 at 20671), while nonabrasive dental gels and rinses do not (45 FR 20666 at 20671).

The agency agrees with the comments that OTC drug monographs should not regulate cosmetic claims and are limited to only drug claims. The monograph definitions are intended to refer to the therapeutic uses of the dosage forms defined. Accordingly, the agency is deleting any references to a ''cosmetic function'' (e.g., cleaning) from the proposed definitions. In the definition for dentifrice, the first sentence (''A substance used with a toothbrush to clean the accessible surfaces of the teeth.'') is deleted. The second sentence is revised to read ''An abrasive-containing dosage form for delivering an anticaries drug to the teeth.'' In the definition for treatment gels, the words ''and are not intended for use in cleaning the teeth'' are deleted. Other definitions mentioned by the comment (treatment rinse, treatment rinse concentrated solution, treatment rinse effervescent tablets, and treatment rinse powder) do not need to be revised because they do not contain any ''cosmetic functions'' language.

6. One comment recommended that the definition of an ''anticaries drug,'' proposed in § 355.3(b) as ''a drug that aids in the prevention of dental cavities (decay, caries),'' be revised to include ''treatment'' in addition to ''prevention'' of dental cavities. The comment also requested that the definition of ''anticaries drug'' reflect the various product dosage forms by adding the following sentence to the definition: ''It may be formulated as an abrasive-containing paste or powder, nonabrasive-containing gel, liquid rinse, or other appropriate product type.'' The comment indicated that the expanded definition more clearly defines an anticaries drug and encompasses the various product dosage forms.

The agency does not agree that the term ''treatment'' alone should be added to the definition of an anticaries drug. In the context of this definition, the word ''treatment'' alone implies that anticaries drug products could treat an existing caries lesion rather than being useful as a preventive treatment. The Panel recommended and the agency previously proposed conditions under which OTC anticaries drug products that aid in the prevention of dental cavities would be generally recognized as safe and effective, and not misbranded (45 FR 20666 at 20690 and 50 FR 39854 at 39871). Treatment of dental cavities is generally understood to be a process by which medical or dental intervention in the management of cavities results in either repair or stabilization of tooth decay. Neither the Panel nor the agency received data indicating that fluoridated compounds included in the monograph are effective in treating or stabilizing tooth decay. The fluoride drugs included in the monograph are intended as preventive measures against tooth decay and not as treatment modalities for the management of existing dental cavities. However, if the term ''treatment'' is expanded to read ''prophylactic treatment,'' the preventive nature of such ''treatments'' would not necessarily imply treatment of an existing caries lesion. Prophylactic treatment is generally described as the act or manner of protection for or prevention of disease. Thus, the agency is adding the term ''prophylactic treatment'' in the definition for ''anticaries drug'' in § 355.3(c) of this final monograph.

The agency does not agree with the comment that the definition of ''anticaries drug'' should specify various dosage forms. The definition is only included in the monograph to reflect the intended use of these drug products.

The agency agrees with the comment that an ''anticaries drug'' can be formulated in various dosage forms and has defined numerous dosage forms in the final monograph (see § 355.3(e) and (h) through (m)). These dosage forms include those requested by the comment.

7. Two comments objected to the second sentence of the definition for ''treatment gel'' in proposed § 355.3(g), which reads: ''Treatment gels are formulated in an anhydrous glycerin base with suitable thickening agents included to adjust viscosity.'' The comments indicated that treatment gels, including 0.4-percent stannous fluoride treatment gel, may be formulated in bases that do not contain any anhydrous glycerin compound without compromising the safety or effectiveness of the anticaries drug product. Therefore, the comments recommended that the agency delete the second sentence of the definition.

The agency does not agree that the second sentence of the definition of a ''treatment gel'' should be deleted. The definition in proposed § 355.3(g) was based on the only formulation for this dosage form that was submitted to the Panel for review. The Panel stated that stannous fluoride is stable in anhydrous glycerin (45 FR 20666 at 20688) and defined ''dental gels'' as being ''formulated in an anhydrous glycerin base with suitable thickening agents included to adjust viscosity'' (45 FR 20690). The Panel (45 FR 20688) and the agency have used this definition based on the results of laboratory and clinical studies that supported the safety and effectiveness of a specific formulation. For greater clarity, the agency is changing the term ''treatment gel'' in § 355.3(i) to ''preventive treatment gel'' to make it clear that the product's intended purpose is prevention of dental cavities. Preventive treatment gels formulated in bases other than anhydrous glycerin could be considered for inclusion in the monograph provided that stability of the fluoride compound is demonstrated and the available fluoride ion is not adversely affected by the base used in the formulation. If such a formulation were found acceptable, the definition of a preventive treatment gel could be revised as necessary to describe such a formulation. However, the agency currently has no data to support such formulations. Accordingly, the agency is not revising the definition at this time.

8. One comment disagreed with the agency's suggestion in the tentative final monograph (53 FR 22430 at 22432) that interested persons may petition the agency to amend the anticaries monograph to include specific organic fluorides as active ingredients for use in dental formulations rather than file to obtain an approved new drug application (NDA). The comment stated that allowing submission of a petition to include organic fluorides in the monograph presupposes that these active ingredients can be shown to be generally recognized as safe and effective, and have been used for a material time and to a material extent. The comment noted that although organic fluoride formulations have been used outside the United States, they do not meet the conditions for inclusion in the OTC drug review because they have never been sold in this country. The comment therefore suggested that the agency not allow the alternative of petitioning to amend the monograph to include organic fluoride formulations, but instead require filing an NDA.

The agency agrees with the comment that organic fluoride formulations do not have a marketing history in the United States. However, the agency is currently reevaluating whether foreign marketing can satisfy the material time and extent criteria for inclusion of an ingredient in the OTC drug review. The agency intends to address this issue in a future issue of the Federal Register. In the meantime, it would not be in the public interest to unduly delay publication of the final monograph for OTC anticaries drug products while this matter is being resolved.

Interested persons may submit a petition requesting amendment of the final anticaries monograph to include an organic fluoride formulation. Such a petition would be considered in the context of the agency's reevaluation of the marketing history threshold criteria for the OTC drug review. Alternatively, an NDA may be filed under part 314 (21 CFR part 314). With either procedure, the manufacturer must submit adequate data showing the organic fluoride to be safe and effective for its intended use.

B. Comments on Specific Anticaries Active Ingredients and Dosage Forms

9. One comment requested that the agency consider the anticaries activities of both the stannous and the fluoride ions in 0.4 percent stannous fluoride, as well as the combined anticaries effect of the total compound, instead of considering the fluoride ions alone. The comment contended that the stannous ions in 0.4 percent stannous fluoride have significant anticaries properties, by reducing enamel solubility and through antibacterial activity. However, the comment did not submit any data to support its position.

The Panel reviewed extensive data on stannous fluoride dentifrices, rinses, and gels (45 FR 20666 at 20684 to 20685 and 20687 to 20688) and attributed effectiveness to the fluoride ion present in the product. The agency is not aware of any data supporting anticaries activity of stannous ions in stannous fluoride. Without data demonstrating this activity, the agency has no basis to consider the stannous ions as contributing to the anticaries effects of these drug products.

10. Several comments requested that the allowable upper limit of fluoride concentration in a dentifrice marketed under the final monograph be increased from 1,150 ppm theoretical total fluorine to 1,500 ppm. The comments stated that 850 to 1,150 ppm levels of fluoride in dentifrice products were

established nearly 25 years ago. One comment mentioned that, at that time, concentrations of fluoride were set arbitrarily low because of concerns about fluoride toxicity. The comments indicated that there is sufficient evidence that much higher fluoride concentrations are safe and effective, based on widespread use of such concentrations in the United States and Europe. With more toxicological data now available, the comments suggested a higher dosage of fluorides in dentifrices should be available for persons who reside in nonfluoridated areas or who have a greater propensity to develop caries. The comments contended that such a need has been acknowledged by the agency's approval of an NDA for an ''extra-strength'' (1,500 ppm) fluoride dentifrice. One comment indicated that it manufactures and distributes ''extra-strength'' fluoride dentifrices in other countries and has received no reports of ill effects from use of these products.

The comments submitted several clinical studies (Refs. 1, 2, and 3) demonstrating that a dentifrice containing 1,500 ppm theoretical total fluorine can provide greater anticaries protection than 850- to 1,150-ppm levels. The first study (Ref. 1) was a 3-year, double-blind clinical comparison of the anticaries effectiveness of a test dentifrice containing 1.14 percent sodium monofluorophosphate (1,500 ppm theoretical total fluorine) with a control dentifrice containing 0.76 percent sodium monofluorophosphate (1,000 ppm theoretical total fluorine). This study involved 2,415 children, primarily 8 to 11 years of age, who resided in a nonfluoridated community. The children were randomly assigned to one of the two groups. The children brushed normally at home and participated in a daily supervised toothbrushing exercise at school. Results of this study indicated that 48 percent of the subjects who used the 1,000-ppm fluoride dentifrice remained caries free and 57 percent of those who used the 1,500-ppm dentifrice remained caries free. The study also suggested that the participants using the 1,000-ppm dentifrice would have projected a savings of 639 additional surfaces and 344 teeth if they had received the 1,500-ppm dentifrice during the 3-year trial.

The second study (Ref. 2) was also a 3-year, double-blind clinical comparison of two sodium monofluorophosphate dentifrices, one containing 1,500 ppm and the other containing 1,000 ppm theoretical total fluorine. The study involved 1,913 children between 6 and 11 years of age. The subjects were randomly assigned to one of the two groups. The children brushed in the same manner as in the first study. Results of this study demonstrated that, even in an area with optimal water fluoridation, a 1,500-ppm concentration provides greater anticaries protection than a 1,000-ppm theoretical total fluorine concentration.

The third clinical study (Ref. 3) compared the anticaries effect of three dentifrices containing the following concentrations of theoretical total fluorine: (1) 1,100 ppm (as sodium fluoride), (2) 2,800 ppm (as sodium fluoride), and (3) 2,800 ppm (as sodium monofluorophosphate). Approximately 4,500 school children between 7 and 15 years of age, whose community water supply contained less than 0.3 ppm fluoride, were assigned at random to brush unsupervised with one of the three dentifrices. Results of the 3-year clinical study showed no significant difference between the 2,800-ppm sodium monofluorophosphate and the positive control (1,100 ppm as sodium fluoride). However, the study demonstrated that the group assigned to brush with sodium fluoride containing 2,800 ppm theoretical total fluoride received an estimated 15 percent fewer cavities than those subjects who brushed with the sodium fluoride dentifrice containing 1,100 ppm theoretical total fluoride.

One comment noted that two of these clinical studies (Refs. 1 and 2) formed the basis for FDA approval of the 1,500-ppm ''extra-strength'' dentifrice under an NDA. Based on these data, the comment requested that the 1,500-ppm dentifrice be included in the monograph.

One comment requested that the agency specifically include higher strength sodium fluoride dentifrice products (1,500 ppm) in the final monograph. The comment stated its belief that consumers should be permitted the widest possible choice of safe and effective OTC drugs and that the monograph should be flexible to permit the use of equivalent fluoride species.

Several other comments argued that increasing the fluoride concentration to a level as high as 1,500 to 1,650 ppm would be unwise without adequate scientific support to justify the increased risk of developing fluorosis. One comment indicated that clinical trials using higher strength fluoride-containing dentifrices have demonstrated no adverse experiences or changes of any consequence with respect to soft tissue aberrations in children 8 to 12 years of age. However, the comment added that there has not been sufficient attention paid to the potential risk of enamel fluorosis in children under 6 years of age using such higher strength fluoride dentifrices, particularly if the children live in an optimally-fluoridated community. Another comment cited two reports (Refs. 4 and 5) indicating that the prevalence of dental fluorosis in children residing in nonfluoridated areas has increased appreciably during the past decade with more than 20 percent of the children having mild fluorosis. The comment also cited another study (Ref. 6) suggesting that the use of fluoride dentifrices prior to 2 years of age is a major risk factor for dental fluorosis. The comment pointed out that modifying the monograph to permit the use of elevated fluoride concentrations in dentifrices (i.e., 1,500 to 1,650 ppm) would clearly increase the risk of children developing dental fluorosis. The comment further stated that the modest increase in anticaries effectiveness attributable to elevated fluoride levels in dentifrices may not be adequate to justify the increased risk of developing fluorosis. The comment concluded that the proposed increase of fluoride in dentifrices to 1,500 ppm would affect the risk/benefit ratio unfavorably. Accordingly, the comment urged the agency to reject the proposed increase in the fluoride level in dentifrices to 1,500 to 1,650 ppm.

Another comment expressed similar concern for the potential risk of enamel fluorosis in children under 6 years of age who may use dentifrices containing the proposed higher levels of fluoride during toothbrushing. The comment indicated that there exists ample documentation that young children swallow a significant amount of dentifrice. The comment submitted two published clinical studies (Refs. 7 and 8) evaluating the significance of fluoride dentifrices as a risk factor in dental fluorosis. One study (Ref. 7) indicated that a portion of the dentifrice introduced to the mouth and not expectorated, but swallowed and absorbed, ranged from 0 to 100 percent. The study suggested that inadequate control of the swallowing reflex by younger children accounts for the excessive ingestion of fluorides, particularly from dentifrices and mouthrinses. The other study (Ref. 8) indicated that, on average, children used 0.662 gram (g) of dentifrice and ingested 0.299 g per brushing. Results from this study indicated: (1) The younger the children, the more likely they are to swallow a greater proportion of dentifrice; and (2) young children who rinse their mouths and expectorate properly after brushing ingest less

dentifrice. The comment predicted that if manufacturers are allowed to market an increased level of fluoride without requiring an agency-approved application, routine use of these extra strength dentifrices would increase the potential risk of enamel fluorosis in younger children. However, the comment did not indicate how or why the routine use of NDA-approved extra strength dentifrice products would prevent an increased risk of enamel fluorosis in younger children.

In the tentative final monograph for OTC anticaries drug products (53 FR 22430 at 22432), the agency stated that a 1,500-ppm theoretical total fluoride level is safe, but indicated that general recognition of the effectiveness of this strength fluoride dentifrice must be based on adequate published or publicly available medical and scientific data. Two clinical studies (Refs. 1 and 2) that formed the basis of an agency NDA approval of this strength sodium monofluorophosphate dentifrice have now been included in the public record for this rulemaking by the NDA holder. Results of these studies indicate an enhanced anticaries benefit derived over a 3-year period from the use of the higher fluoride sodium monofluorophosphate dentifrice (1,500 ppm) when compared to the positive control fluoride dentifrice (1,000 ppm). The studies also indicated that children who are at increased risk to develop caries and those with erupting premolars and second molars may derive more benefit from a 1,500-ppm dentifrice than a 1,000-ppm dentifrice.

The agency has not received any clinical or available fluoride ion data on any 1,500-ppm sodium fluoride dentifrice comparable to the information for 1,500-ppm sodium monofluorophosphate dentifrice. Therefore, the agency is not including higher strength (1,500 ppm) sodium fluoride dentifrice drug products in this final monograph at this time.

As noted above, comments expressed concern that an increase of theoretical total fluorine to 1,500 ppm could increase the incidence of dental fluorosis in children. The agency agrees that for children under 6 years of age a risk/benefit analysis indicates that levels of fluoride in dentifrices should not exceed the currently accepted OTC level of 1,150 ppm (see discussion of fluorosis in comment 23). Although an NDA was approved in 1986 for an extra-strength fluoride dentifrice (1,500 ppm) whose labeling allowed for use in children above 2 years of age, the agency recognizes that more recent data (Refs. 4 and 8) suggest that the incidence of fluorosis in children under 6 years of age is increasing in the United States. The agency does not believe that the increased risk of fluorosis outweighs the benefit of using an extra-strength fluoride dentifrice in children under 6 years of age. The agency has determined from the results of the submitted clinical studies that the enhanced benefit of using an extra-strength dentifrice product does not present additional risk to children above 6 years of age and to adults, particularly for those with a greater propensity to develop cavities or for those who live in communities with nonfluoridated water. As discussed in the tentative final monograph (50 FR 39854 at 39864), developing teeth of children under 6 years of age may show objectionable dental fluorosis from repeated ingestion of excessive amounts of fluoride. However, epidemiological and clinical findings indicate that the formative state of the teeth of children 6 years of age and older (excepting third molars) is too advanced to be affected by the amount and frequency of use of fluoride dentifrices.

The agency is including sodium monofluorophosphate dentifrices that contain 1,500 ppm theoretical total fluorine in this final monograph. Because of concerns about dental fluorosis, the agency is requiring that dentifrice products with these fluorine concentrations be clearly labeled for use only by children above 6 years of age. Accordingly, the agency is including the following directions in § 355.50(d)(1)(ii):

Paste dosage form with a theoretical total fluorine concentration of 1,500 ppm identified in § 355.10(b)(2). Adults and children 6 years of age and older: brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Do not use unless directed by a dentist or doctor.

The agency believes that extra-strength fluoride dentifrice products may be beneficial to consumers who have a greater propensity to develop cavities, and that manufacturers may wish to promote these products for this purpose. Therefore, the agency is expanding § 355.50(f)(2) to include an optional additional labeling statement for these products as follows:

For dentifrice products containing 1,500 ppm theoretical total fluorine. Adults and children over 6 years of age may wish to use this extra-strength fluoride dentifrice if they reside in a nonfluoridated area or if they have a greater tendency to develop cavities.

Finally, the agency does not find that sufficient data exist to support the safety and effectiveness of a theoretical total fluorine level above 1,500 ppm. Accordingly, the agency is not including dentifrices with such theoretical total fluorine levels in the monograph.

References

(1) Conti, J. A. et al., ''A 3-year Clinical Trial to Compare Efficacy of Dentifrices Containing 1.14 Percent and 0.76 Percent Sodium Monofluorophosphate,'' *Community Dental Oral Epidemiology*, 16:135–138, 1988.

(2) Fogels, H. R. et al., ''A Clinical Investigation of a High-Level Fluoride Dentifrice,'' *Journal of Dentistry for Children*, 55(3):210–215, 1988.

(3) Lu, K. H. et al., ''A Three-year Clinical Comparison of a Sodium Monofluorophosphate Dentifrice with Sodium Fluoride Dentifrices on Dental Caries in Children,'' *Journal of Dentistry for Children*, 54(4):241–244, 1987.

(4) Woolfolk, M. W. et al., ''Relation of Sources of Systemic Fluoride to Prevalence of Dental Fluorosis,'' *Journal of Public Health Dentistry*, 49:78–82, 1989.

(5) Leverett, D. H., ''Fluorides and the Changing Prevalence of Dental Caries,'' *Science*, 217:26–30, 1982.

(6) Osuji, O. O. et al., ''Risk Factors for Dental Fluorosis in a Fluoridated Community,'' *Journal of Dental Research*, 67(12):1488–1492, 1988.

(7) Whitford., G. M., D. W. Allmann, and A. R. Shahed, ''Topical Fluorides: Effects on Physiologic and Biochemical Processes,'' *Journal of Dental Research*, 66(5):1072–1078, 1987.

(8) Simard, P. L. et al., ''The Ingestion of Fluoride Dentifrice by Young Children,'' *Journal of Dentistry for Children*, 56:177–181, 1989.

11. One comment (from the holder of the only approved NDA for a 1,500-ppm fluoride dentifrice) provided data indicating that the lowest available fluoride ion concentration measured during the 3-year clinical trial of its 1,500-ppm sodium monofluorophosphate dentifrice product was 1,295 ppm, with an analytical variability of ± 20 ppm (Refs. 1 and 2).

Based on the available fluoride ion data for this product, the agency has determined at this time that all 1,500-ppm sodium monofluorophosphate dentifrices must provide an available fluoride ion concentration equal to or greater than 1,275 ppm. Accordingly, the agency is including higher strength (1,500 ppm) sodium monofluorophosphate dentifrice products in § 355.10(b)(2) of this final monograph as follows:

Dentifrices containing 1,500 ppm theoretical total fluorine in a paste dosage form. Sodium monofluorophosphate 1.153 percent with an available fluoride ion concentration (consisting of $PO_3F^{=}$ and F^{-} combined) ≥ 1,275 ppm.

References

(1) Comment LET18, Docket No. 80N–0042, Dockets Management Branch.
(2) Comment LET20, Docket No. 80N–0042, Dockets Management Branch.

12. One comment requested that the active ingredient listings for sodium fluoride treatment rinses in proposed § 355.10(b)(3), (b)(4), and (b)(5) be combined as follows: ''Sodium fluoride 0.02 to 0.05 percent in a final solution with a pH of approximately 7.'' The comment stated that this would provide a range of allowable concentrations for these rinses without affecting the technical accuracy of the monograph.

The agency disagrees with the comment. The active ingredient listings in § 355.10(b)(3), (b)(4), and (b)(5) specify particular concentrations for sodium fluoride in a rinse dosage form. The monograph is not intended to provide a range of concentrations for these products. The 0.02- and 0.05-percent sodium fluoride concentrations were included in the monograph based on separate, independent clinical studies, as discussed for the 0.05-percent concentration in the Panel's report (45 FR 20666 at 20686) and for the 0.02-percent concentration in the agency's tentative final monograph (50 FR 39854 at 39863). More importantly, the directions for 0.02 percent sodium fluoride in a neutral dental rinse (pH of approximately 7) are for use twice daily and for 0.05 percent sodium fluoride rinse are for use only once a day. These dosage regimens are each supported by separate, independent clinical data. There are no data to support directions for other concentrations. Accordingly, there is no basis to combine the active ingredient listings for the sodium fluoride treatment rinses included in this final monograph.

13. One comment requested that sodium fluoride/sodium bicarbonate powdered dentifrices be included in the final monograph for OTC anticaries drug products. In response to the agency's concerns discussed in the tentative final monograph (53 FR 22430 at 22443) about the safety and effectiveness of powdered fluoride dentifrices, the comment submitted several analytical and biological studies (Ref. 1). The comment contended that these studies demonstrate the effectiveness and comparable bioavailability of a powdered fluoride dentifrice with a toothpaste containing a similar abrasive system and an equivalent concentration of theoretical total fluorine.

The comment submitted several animal studies (Refs. 2, 3, and 4) that determined the anticaries effect of a sodium fluoride/sodium bicarbonate powdered dentifrice in rats that were infected with highly virulent strains of cariogenic bacteria. In one study (Ref. 2), a group of rats infected with *Streptococcus sobrinus* that was treated topically with sodium fluoride/sodium bicarbonate powdered dentifrice experienced 42 percent fewer caries lesions than a control group treated only with distilled water. Rats exposed to either the tooth powder or 10 ppm fluoridated drinking water produced similar reduction in caries (42 and 47 percent, respectively).

In another study (Ref. 3), rats infected with *S. mutans* were treated with a 1:2 part slurry of sodium bicarbonate-based powdered dentifrice containing 0.22 percent sodium fluoride (1,000 ppm) in water for 1 minute daily for 3 weeks. Results indicated a 51-percent caries reduction in infected rats treated with the tooth powder as compared to the group of rats treated with distilled water. Rats treated with an equal concentration of sodium fluoride aqueous solution without other inactive ingredients developed a 36-percent reduction in cavities as compared to the control group. The data also indicated that no significant difference in the incidence of cavities was observed in the group of rats treated topically with sodium fluoride/sodium bicarbonate powdered dentifrice and the group of rats receiving no other treatment except 10 ppm fluoride in their drinking water (51 percent versus 54 percent).

In another animal study (Ref. 4), rats infected with *S. sobrinus* were treated with an undiluted sodium bicarbonate-base powdered dentifrice containing 0.22 percent sodium fluoride. Results of this study indicated a 47-percent reduction in cavities as compared to the control group. This reduction in cavities was not statistically different from the 43-percent reduction in total cavities obtained by topical treatment with an undiluted sodium bicarbonate-based toothpaste containing the same level of sodium fluoride.

The comment also submitted several clinical studies that evaluated the anticaries effectiveness of fluoridated and nonfluoridated powdered dentifrices. However, the studies involving nonfluoridated powdered dentifrices were not related to and do not support the effectiveness of the comment's dentifrice product that contains sodium fluoride as the active ingredient.

The comment submitted a 1-year clinical study (Ref. 5) that demonstrated the anticaries effectiveness of tooth powders containing fluorapatite (essentially calcium fluoride). Although the powdered dentifrice used in this study contained an active ingredient (fluorapatite) different than the active ingredient found in the comment's sodium fluoride dentifrice product, the study supported the anticaries effectiveness of a powdered dentifrice dosage form. In this study, 150 medical students brushed daily with one of three dentifrices containing: (1) 71.4 percent fluorapatite, (2) an ion-free ''synthetic apatite'' consisting of hydroxyapatite with a surface layer of fluorapatite (total fluorine content, 0.25 percent), or (3) a control powdered dentifrice not containing fluoride. Results of this study indicated that the group that brushed with the fluorapatite powder and the group that bushed with the ''synthetic apatite'' paste developed an average of 38 and 67 percent fewer cavities, respectively, than those students who brushed with the nonfluoride tooth powder.

Another study (Ref. 6) compared human enamel uptake of fluoride from a sodium fluoride/sodium bicarbonate dentifrice in a powdered and a paste dosage form. In this study, human enamel was ground and polished flat to provide a uniform surface and then demineralized to create a simulated white-spot caries lesion. Several enamel slabs were exposed continuously for 30 minutes at body temperature to a tooth powder (with a poured-bulk density of 1.0 to 1.2 g/milliliter (mL) and available fluoride ion concentration equal to or greater than 850 ppm) and a toothpaste containing sodium fluoride/sodium bicarbonate with an available fluoride ion concentration equal to or greater than 650 ppm. Results of this study indicated that both the powder and paste dosage forms demonstrated comparable enamel uptake of fluoride ions.

The comment concluded by stating that the data demonstrate the safety and effectiveness of a powdered dentifrice containing sodium fluoride and show that such a product can provide effectiveness equivalent to a toothpaste containing a similar abrasive system. The comment urged the agency to include sodium fluoride/sodium bicarbonate powdered dentifrices in the final monograph for OTC anticaries drug products.

The agency has reviewed the data provided by the comment and determined that sufficient data have been provided to generally recognize as safe and effective powdered dentifrices containing sodium fluoride with a sodium bicarbonate abrasive. However, the agency points out that several of the studies submitted measured the anticaries effectiveness of dentifrices containing active agents (fluorapatite, carbamide-urease, and fluoridated table

salt) different than the active ingredient contained in the comment's tooth powder (sodium fluoride). Although the data from one study provide some indication of cariostatic effectiveness of a fluorapatite dentifrice, the agency does not find these studies pertinent to the determination of the safety and effectiveness of the comment's sodium fluoride/sodium bicarbonate powdered dentifrice.

The agency considers the biological studies submitted by the comment as demonstrating that the bioequivalence and bioavailability of fluoride ions are comparable for sodium fluoride/sodium bicarbonate powdered and paste dentifrices containing the same concentration of theoretical total fluorine. Results of several well-designed animal caries studies (Refs. 2, 3, and 4) demonstrate that rats inoculated with cariogenic bacteria and fed a caries promoting diet developed 42 to 51 percent fewer cavities when treated with a topical application of sodium fluoride/sodium bicarbonate powdered dentifrice than rats in a control group. In addition, the agency concludes that the results of the submitted human enamel uptake study (Ref. 6) indicate that the measured human enamel uptake of fluoride from a powder containing sodium fluoride/sodium bicarbonate with a fluoride ion concentration of 1,000 ppm was better than the fluoride uptake of a similar dentifrice paste formulation. Although the agency does not believe that this system is comparable to real-life development of early dental caries or that a one-time exposure of enamel slabs continually for 30 minutes at 37 °C simulates real-life conditions of short, intermittent exposures during a month's usage, the agency does believe that fluoride uptake is a marker of potential anticaries effectiveness and considers the two fluoride dosage forms at least equivalent.

Accordingly, the agency is including sodium fluoride/sodium bicarbonate powdered dentifrices in § 355.10(a)(2) of this final monograph as follows:

Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a powdered dosage form: Sodium fluoride 0.188 to 0.254 percent with an available fluoride ion concentration of ≥ 850 ppm for products containing the abrasive sodium bicarbonate and a poured-bulk density of 1.0 to 1.2 grams per milliliter.

References

(1) Comment No. C00066, Docket No. 80N–0042, Dockets Management Branch.

(2) Tanzer, J. M. et al., ''Effects of Bicarbonate-based Dental Powder, Fluoride, and Saccharin on Dental Caries and on *Streptococcus sobrinus* Recoveries in Rats,'' *Journal of Dental Research*, 66(3):791–794, March, 1987.

(3) Tanzer, J. M. et al., ''Bicarbonate-based Dental Powder, Fluoride, and Saccharin Inhibition of Dental Caries Associated with *Streptococcus mutans* Infection of Rats,'' *Journal of Dental Research*, 67(6):969–972, June, 1988.

(4) McMahon, T. et al., ''Caries Inhibition by Bicarbonate-based Dental Powder in *S. mutans* 10449S-infected Rats,'' *Journal of Dental Research*, 67:343, 1988.

(5) McClendon, J. F., and W. C. Foster, ''Prevention of Dental Caries by Brushing The Teeth With Powders Containing Fluorapatite,'' *Journal of Dental Research*, 26:233–239, 1947.

(6) Letter from J. J. Hefferren, J. J. Hefferren Resources, Inc., to T. Winston, Church & Dwight Co., Comment No. C00066 (Attachment 1), Docket No. 80N–0042, Dockets Management Branch.

14. One comment responded to the agency's concern expressed in the tentative final monograph (53 FR 22430 at 22444) that several possible methods of applying a powdered dosage form to a toothbrush may lead to significant variations of fluoride ion delivered to the teeth. The comment agreed that directions for using powdered products have been varied. However, the comment indicated that this is not a reason to determine that a sodium fluoride powdered dentifrice would not be safe and effective. The comment added that after several years of marketing a powdered dentifrice, it has found that pouring a powdered dentifrice from a container with a flip-top spout provides a cleaner and simpler application of the product with a uniform dosage of fluoride.

The comment claimed that the available fluoride ion obtained from two applications of a tooth powder containing a minimum of 850 ppm soluble (available) fluoride ion will be equal to or greater than the Panel's recommended 650 ppm available fluoride ion for sodium fluoride dentifrices. The comment based the need for two applications of tooth powder on its recommendation that sodium fluoride/sodium bicarbonate powdered dentifrices have a poured-bulk density of 1.0 to 1.2 g/mL and an available fluoride ion concentration equal to or greater than 850 ppm. The comment responded to several concerns raised by the agency in the tentative final monograph (53 FR 22430 at 22443). These concerns involved previous recommendations that two poured-bulk density ranges (0.5 to 0.99 g/mL and 1.0 to 1.7 g/mL) were necessary for powdered fluoride dentifrices and that two applications per brushing with a powdered dentifrice in the lower poured-bulk density range would provide an appropriate dose of fluoride. The comment stated that the two poured-bulk density ranges were based on the assumption that equal volumes of tooth powder and toothpaste are applied in a single application to the brush; however, that assumption may no longer be correct because of the difference in consistency of the two dosage forms. The comment mentioned that more toothpaste than tooth powder can be applied to a brush without falling off; thus, the level of fluoride delivered to the teeth in one application is greater with a toothpaste than with a tooth powder, assuming comparable theoretical total fluorine.

The comment submitted a study (Ref. 1) that measured the weight of tooth powder and toothpaste applied in a single application to a tooth brush. Subjects were instructed to generously pour tooth powder onto a wet toothbrush so that the bristles were completely covered. The subjects were also instructed to apply to a similar size brush an amount of toothpaste they would normally use during brushing. The weight of dental powder in a single application was determined by weighing the toothbrush (plus a piece of paper used to catch spillage) before and after application; whereas the weight of the toothpaste was determined by weighing the package before and after applying a single dose to a toothbrush. The results of this study indicated that consumers applied an average of 0.8 g of powdered dentifrice and 1.46 g of paste to the same type of toothbrush. Results of this study indicated that two applications of a powdered dentifrice product of poured-bulk density 1.1 g/mL provides a level of fluoride comparable to a single application of a fluoridated toothpaste containing the same fluoride concentration.

The data were further analyzed (Ref. 2) to determine what dosage of fluoride would be provided if two applications of tooth powder with an available fluoride concentration of 850 to 1,100 ppm were placed on a toothbrush. The comment stated that, assuming two applications of tooth powder and one of toothpaste, the extrapolated amount of available fluoride ion delivered to the teeth by the tooth powder is comparable to the amount of soluble fluoride ion provided by a toothpaste. Based on these data, the comment recommended that the directions specify two applications of fluoride powder dentifrices containing 850 to 1,100 ppm theoretical total fluorine and a poured-bulk density range of between 1.0 and 1.2 g/mL.

One comment discussed directions for use of powdered fluoride dentifrices by children under 12 years of age. In the

tentative final monograph (53 FR 22430 at 22444), the agency had stated that children under 12 years of age may require greater manual dexterity to properly use a powdered dentifrice than is needed to correctly use a toothpaste. The agency expressed concern about the potential for young children to accidentally consume a toxic amount of fluoride when using a tooth powder compared to a toothpaste. The comment contended that powdered dentifrices do not pose any greater risk over pastes for accidental overdoses by children. The comment added that, while it believes that children between 6 and 12 years of age can use a powdered dentifrice properly, it has no objection to the monograph providing that powdered dentifrices not be labeled for use by children under 6 years of age and requiring labeling that states use by children 6 to under 12 years of age should be only with adult supervision. However, the comment expressed concern that such labeling might give the false impression that there is an inherent unsafe quality with the product, rather than merely a difficulty for children to use the product properly. The comment suggested the monograph include the following directions and labeling for powdered fluoride dentifrices to prevent any such false impressions: ''Since a powdered fluoride dentifrice may be difficult for children to use, this product is not recommended for children under 6. Children between the ages of 6 and 12 should use this product under adult supervision.''

The agency has reviewed the data (Refs. 1 and 2) and determined that the directions for use of fluoride powdered dentifrices with a poured-bulk density of 1.0 to 1.2 g/mL and an available fluoride ion concentration equal to or greater than 850 ppm must specify two applications to deliver a comparable amount of fluoride as a fluoride toothpaste of the same strength. One study (Ref. 1) showed that in a single application 45 percent less tooth powder than toothpaste was applied to a similar size brush. Because spillage that occurred during the weighing procedure was included in the final applied weight of powder, even less tooth powder than toothpaste was actually placed on the brush. Thus, the agency agrees with the comment that consumers who use two applications of a fluoride tooth powder with a poured-bulk density of 1.0 to 1.2 g/mL containing 850 to 1,100 ppm available fluoride ion receive an amount of fluoride ion comparable to using a single application of a sodium fluoride toothpaste with an available fluoride ion concentration equal to or greater than 650 ppm. Accordingly, the agency is including directions in this final monograph that provide for two applications of fluoride powdered dentifrices. The agency is also including in the LTP tables a poured-bulk density range of 1.0 to 1.2 g/mL for powdered dentifrices (see section I.F., comment 37 of this document).

Regarding the use of powdered fluoride dentifrices by children, the agency does not believe that powdered fluoride dentifrices pose a greater threat for accidental ingestion than fluoride toothpaste. Also, the agency does not believe that children 6 years of age and older are likely to consume a toxic amount of fluoride from a dentifrice powder. In most instances, such products will be used under adult supervision. Further, existing regulations (§ 310.201(a)(10)(iv)) establish package size limitations for sodium fluoride preparations.

The agency agrees with the comment that these products should not be labeled for use by children under 6 years of age, and should be labeled for use with adult supervision by children 6 to under 12 years of age. Accordingly, the agency is adding the following directions for powdered dentifrices in § 355.50(d)(1)(iii):

Powdered dosage form with a theoretical total fluorine concentration of 850 to 1,150 ppm identified in § 355.10(b)(2). Adults and children 6 years of age and older: Apply powder to a wet toothbrush; completely cover all bristles. Brush for at least 30 seconds. Reapply powder as before and brush again. Rinse and spit out thoroughly. Brush teeth, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Do not use unless directed by a dentist or doctor.

The agency believes that these directions will not give consumers a false impression that there is any inherent unsafe quality with these products.

References

(1) J. Ross Associates, ''A Dentifrice Use Test,'' draft of unpublished study, Comment No. C00066 (Attachment I, Exhibit 5), Docket No. 80N–0042, Dockets Management Branch.

(2) J. Ross Associates, ''A Dentifrice Use Test,'' draft of unpublished study, Comment No. C00066 (Attachment I, Exhibit 7), Docket No. 80N–0042, Dockets Management Branch.

15. One comment agreed with the agency's concern expressed in the tentative final monograph (53 FR 22430 at 22444) that proper packaging is important to prevent moisture contamination of a powdered dentifrice, particularly in areas where the humidity is high due to showering and bathing. The comment indicated that its powdered dentifrice product is sold in a plastic bottle with a flip top cap and, therefore, quite effectively prevents moisture contamination.

As discussed in the tentative final monograph (53 FR 22444), the agency agrees with the comment that powdered fluoride dentifrices would probably remain more stable for a longer period of time than the paste form because there would be less interaction between dry ingredients during storage of the dentifrice. However, the agency recognizes that the storage conditions of a powdered fluoride dentifrice would have a significant impact on whether the product would remain stable longer than the paste form. Storage of the powdered product in areas where the humidity is high due to showering and bathing would require that the container be resistant to moisture contamination.

A ''tight container,'' as defined in the United States Pharmacopeia (U.S.P.), would meet this criterion. The U.S.P. defines a ''tight container'' (Ref. 1) as a container that ''protects the contents from contamination by extraneous liquids, solids, or vapors, from loss of the article, and from efflorescence, deliquescence, or evaporation under the ordinary or customary conditions of handling, shipment, storage, and distribution, and is capable of tight re-closure.''

In addition, § 211.94 (21 CFR 211.94) of the FDA current good manufacturing practice (GMP) regulations addresses drug product containers and closures. Section 211.194(a) states: ''Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements.'' Section 211.194(b) states: ''Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.''

Therefore, based on § 211.94 of the FDA GMP regulations and the U.S.P. standard for a ''tight container,'' the agency is adding a new paragraph in § 355.20(b) that reads: ''*Tight container packaging.* To minimize moisture contamination, all fluoride powdered dentifrices shall be packaged in a tight container, which is defined as a container that protects the contents from contamination by extraneous liquids, solids, or vapors, from loss of the article, and from efflorescence, deliquescence,

or evaporation under the ordinary or customary conditions of handling, shipment, storage, and distribution, and is capable of tight reclosure.''

Reference

(1) *The United States Pharmacopeia 23—The National Formulary 18*, United States Pharmacopeial Convention, Inc., Rockville, MD, p. 10, 1994.

C. Comments on Labeling of OTC Anticaries Drug Products

16. One comment responded to the agency's question whether consumers would benefit in having OTC fluoride-containing drug products labeled to state their fluoride levels. The comment objected to fluoride level labeling for OTC anticaries drug products and provided the results of a consumer survey as support (Ref. 1). The survey was conducted in shopping malls in eight different geographic areas and included a sample of 200 women between the ages of 18 and 49. The women routinely purchased dentifrice products for their households. In addition, 150 women with children between 1 and 5 years of age were interviewed to determine the habits and practices of women with children regarding the use of fluoride dentifrices. The comment stated that the results of the survey indicate that: (1) Consumers believe that fluoride in dentifrice products is important in preventing cavities, (2) regardless of the unit of measurement, e.g., ppm, percent, or milligrams per inch (mg/in), used to label the fluoride concentration, consumers believe ''more is better'' when choosing a dentifrice because they consistently selected dentifrices labeled with the higher net fluoride, indicating that consumers believe that there are differences in the effectiveness of fluoride dentifrice products, (3) most consumers know how to use fluoride dentifrices, (4) most consumers are aware of the fluoride ingredient in the toothpaste, and (5) most parents take an interest in and supervise their children's brushing habits. Based on these results, the comment concluded that labeling fluoride-containing products to state their fluoride levels is not useful to consumers and could be misleading. The comment recommended that such labeling not be required for OTC fluoride drug products.

The agency has evaluated the consumer survey and determined that it has some methodology deficiencies. The major deficiency is an inadequate respondent sample size. In order to generalize the findings of this study to the general population, it would be necessary to have a larger number of respondents. Further, the survey involved only women between the ages of 18 and 49 years of age. There were no men in the survey nor women above 49 years of age; these people might also have reasons for wanting to know the fluoride content. In addition, the survey did not attempt to assess the relative understanding by the respondents of the various methods of expressing quantities of fluoride. Contextual material could have been used to clarify the meaning of the measures used, making it more likely that consumers could make use of the information provided, regardless of the type of measurements used.

Nonetheless, the survey provides some useful information. It demonstrates that more consumers chose a dentifrice labeled with the higher net fluoride content, based on the concept that ''more fluoride is better.'' Rather than emphasizing fluoride concentration numbers, the agency believes that labeling would be more beneficial if it informs consumers who have a greater propensity to develop cavities of the need to use a higher strength fluoride dentifrice. Therefore, in this final rule, the agency is including in § 355.50(f)(2) the following optional additional labeling statement for dentifrice products containing 1,500 ppm theoretical total fluorine: ''Adults and children over 6 years of age may wish to use this extra-strength fluoride dentifrice if they reside in a nonfluoridated area or if they have a greater tendency to develop cavities.'' Because of concerns about dental fluorosis occurring in children under 6 years of age, the agency is requiring extra-strength fluoride dentifrice products to state in their labeling that the product should not be used by children under 6 years of age unless directed by a doctor or dentist. (See section I.B., comment 10 of this document.)

In conclusion, no comments, data, or information were submitted in support of fluoride level labeling. Accordingly, this final monograph does not contain a requirement that fluoride-containing dentifrice products label the quantity of fluoride. However, it does provide an optional additional labeling statement that manufacturers may use for these products.

Reference

(1) Comment No. C0097, Docket No. 80N–0042, Dockets Management Branch.

17. One comment objected to the inclusion of the term ''treatment'' as the single recommended term in the proposed statement of identity in § 355.50(a). The comment stated that the terms ''treatment'' and ''dental'' are both appropriate statements of identity for various anticavity product dosage forms and that other equally truthful and nonmisleading identifiers are also appropriate. The comment made two recommendations: (1) The term ''treatment'' be retained as an optional statement of identify for gels, rinses, concentrated rinses, rinse powders, or rinse effervescent tablets, and (2) the term ''dental'' also be listed as optional, such as in connection with a professionally promoted ''dental treatment gel.'' The comment concluded that its suggested revisions to § 355.50(a) would provide for truthful and accurate statements of identity.

Another comment suggested that the agency delete the term ''treatment'' from the statement of identity and permit ''anticavity dental rinse'' or ''fluoride dental rinse'' as a statement of identity, because the term ''treatment'' does not appropriately describe the activity of these products. The comment stated that these rinse products provide their anticaries benefits primarily through a prophylactic mode of action and are perceived by consumers as preventive prophylactic measures rather than therapeutic treatments. The mechanism of fluoride action is well recognized in the scientific community and was addressed in the Panel's report (45 FR 20666 at 20672). According to the comment, the Panel noted that fluoride increases enamel resistance to acid solubility, making the teeth less susceptible to plaque acid attack, thereby producing its cariostatic effect. The comment concluded this is primarily a preventive mode of action as contrasted to a therapeutic action. The comment thus proposed that the agency delete the term ''treatment'' from the statement of identity and permit ''anticavity dental rinse'' or ''fluoride dental rinse'' as a statement of identity. The comment concluded that these statements of identity are more descriptive and meaningful to consumers and more accurately define the therapeutic benefit of an anticaries drug product.

The agency discussed the use of the term ''treatment'' as part of the statement of identity for nonabrasive gels and rinses in the tentative final monograph (50 FR 39854 at 39866) in response to a comment that pointed out that some current dentifrice (abrasive-containing) products are transparent or translucent and are called gels by manufacturers and consumers. Two other comments also expressed concern that the use of the term ''gel'' alone for a nonabrasive 0.4-percent stannous fluoride product could be confusing to

the consumer in distinguishing between abrasive and nonabrasive fluoride gels; these comments suggested the term ''nonabrasive dental gel.'' The agency agreed with the comments that it is important to provide labeling that would allow consumers to easily distinguish between a nonabrasive and an abrasive-containing fluoride gel, but stated that the term ''nonabrasive'' may not be meaningful for consumers. The agency also stated that because nonabrasive fluoride gels had not been widely marketed, consumers were not familiar with the use of the term ''dental gel'' to identify such products, particularly in the context of widely marketed abrasive-containing fluoride dentifrices labeled as gels. Thus, the agency proposed that the term ''treatment'' be included in the statement of identity for all nonabrasive OTC fluoride products to clearly distinguish between a dentifrice and a nonabrasive fluoride product.

The agency agrees with the comment that the term ''treatment'' can be optional for fluoride dental rinses, but disagrees with making this term optional for nonabrasive fluoride gels. As discussed in section I.A., comment 7 of this document, the agency has added the word ''preventive'' to the definition of a ''treatment gel.'' The comments did not discuss the possibility that consumers could be confused in distinguishing a nonabrasive fluoride treatment gel from an abrasive-containing dentifrice gel. The comment also did not explain how such labeling would distinguish a nonabrasive fluoride gel from an abrasive fluoride dentifrice. In order for consumers to be better able to make this distinction, the agency is requiring that the term ''preventive treatment'' be included in the statement of identity for nonabrasive fluoride gels. Because a distinction is not needed for fluoride dental rinses, the agency is providing that the phrase ''preventive treatment'' be optional in the statement of identity for these products. The statement of identity for OTC anticaries drug products in § 355.50(a) of this final monograph reads as follows:

The labeling of the product contains the established name of the drug, if any, and identifies the product as the following: ''anticavity fluoride'' (select one of the following as appropriate: ''dentifrice,'' ''toothpaste,'' ''tooth polish,'' ''tooth powder;'' (optional: ''dental'') ''preventive treatment gel;'' or (optional: ''preventive treatment'' or ''dental'')) (select one of the following: ''rinse,'' ''concentrated solution,'' ''rinse powder,'' or ''rinse effervescent tablets''). The word ''mouthwash'' may be substituted for the word ''rinse'' in this statement of identity if the product also has a cosmetic use, as defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(i)).

18. One comment requested revisions in the proposed statement of identity for fluoride-containing products in § 355.50(a). The comment contended that a fluoride-containing liquid product labeled both to prevent cavities and to freshen the breath should be identified as an ''anticavity or fluoride mouthwash,'' whereas a fluoride rinse that makes no cosmetic claims should properly be identified as an ''anticavity or fluoride rinse.''

Several other comments requested that the statement of identity for anticaries drug products include the terms ''tooth powder'' and ''tooth polish.'' The comments stated that these terms are commonly recognized and have been used in dentifrice product labeling for many years.

The agency agrees that a fluoride-containing liquid product represented both to prevent cavities and to freshen the breath can properly be identified as an ''anticavity or fluoride mouthwash.'' Further, the agency agrees that a fluoride rinse with no cosmetic claims in its labeling is appropriately identified as a ''rinse.'' The agency also agrees that the terms ''tooth polish'' and ''tooth powder'' are suitable for use as part of the statement of identity for anticaries drug products. The word ''tooth'' indicates the site of usage; ''powder'' is a dosage form; and ''polish'' has been used in labeling of these products for many years without consumer confusion. The word ''polish'' indicates a cosmetic usage. As discussed in comment 19, the agency's OTC drug regulations do not prohibit placing a cosmetic statement of identity of a drug/cosmetic product on the principal display panel. Accordingly, the agency is including the terms ''mouthwash'' (if the product also has a cosmetic use), ''tooth polish,'' and ''tooth powder'' in § 355.50(a) in this final rule. (For further discussion of the statement of identity, see section I.C., comments 17 and 19 of this document.)

19. Two comments noted that many anticaries drug products also properly contain cosmetic ingredients and include cosmetic labeling. The comments contended that manufacturers must be permitted to label such products with statements of identity that include truthful drug/cosmetic terminology. For example, the comments stated that the same product may be used both as an anticaries dentifrice and as a cleaning and breath freshening toothpaste. The comment maintained that such a product should be able to truthfully declare in its statement of identity what it is and what it does.

One comment maintained that the agency's labeling policy set forth in a proposal to amend the statement of identity requirements for OTC drugs published in the Federal Register of April 17, 1986 (51 FR 13023), along with the agency's exclusivity and label separation policies, make it impossible for a manufacturer to comply with both the drug and cosmetic labeling requirements set forth in the statute and regulations. The comment pointed out that existing FDA regulations require that the statement of identity for both drug and cosmetic products appear on the principal display panel of the product. The comment contended that the effect of the agency's drug-cosmetic label separation policy is that the cosmetic statement of identity may not be placed on the principal display panel.

The comment argued that cosmetic terminology should be allowed anywhere in the labeling of an anticaries dentifrice that is also a cosmetic product so long as it does not render the product's labeling false or misleading. The comment argued that consumers would not be misled by the inclusion of both kinds of labeling on an anticaries drug product. On the contrary, the comment stated that consumers would more likely be misled if the drug and cosmetic statements of identity and other claims were to appear on entirely different portions of the label. The comment concluded that there is no legal or policy justification for this label separation policy.

If a product covered by this rulemaking is marketed for both drug and cosmetic use, it must conform to the requirements of the final OTC drug monograph and bear appropriate labeling for cosmetic uses in accord with section 602 of the act (21 U.S.C. 362) and the provisions of 21 CFR parts 701 and 740.

Sections 201.61 and 701.11 of the CFR require that the statement of identity for OTC drug and cosmetic products each appear on the principal display panel of the product. The agency's OTC drug regulations do not prohibit placing the cosmetic statement of identity of a drug/cosmetic product on the principal display panel. However, in accordance with the revised labeling requirements for OTC drug products, cosmetic claims may not appear within the boxed area designated ''APPROVED USES.'' (See section I.A., comment 1 of this document.) As discussed in the final rule on the agency's ''exclusivity policy'' (51 FR 16258 at 16264 (paragraph 14)), cosmetic terminology is

not reviewed and approved by FDA in the OTC drug monographs and therefore can not be placed in the boxed portion of the label. Cosmetic terminology can, however, be placed outside the box and on the product's principal display panel. In addition, cosmetic claims may appear elsewhere in the labeling should manufacturers choose the labeling alternative provided in § 330.1(c)(2)(i) or (c)(2)(iii) for labeling drug/cosmetic products. Although the agency does not specifically prohibit commingled drug and cosmetic labeling other than in the product's indications section, such claims should be appropriately described so that consumers will be readily able to differentiate the drug aspects from the cosmetic aspects of such labeling. If commingled drug and cosmetic labeling claims are confusing or misleading, the product's labeling could be misleading within the meaning of sections 502(a) and 602(a) of the act (21 U.S.C. 352(a) and 362(a)).

20. One comment objected to the first portion of the agency's proposed additional labeling statement for fluoride dental rinses in § 355.50(e)(2), which states: ''This is a(n)'' (select one or both of the following: ''anticavity'' or ''fluoride'') ''treatment rinse, not a mouthwash. Read directions carefully before using.'' The comment contended that a properly formulated and labeled product could be legally and accurately promoted as both an anticavity dental rinse and a cosmetic mouthwash. The comment added that requiring the ''not a mouthwash'' statement on fluoride dental rinses is not consistent with the agency's well-established policy regarding OTC drugs that claim both therapeutic and cosmetic benefits. The comment stated that dual drug/cosmetic labeling is permitted in other product categories (e.g., antiperspirants, dentifrices, and antidandruff shampoos), and that the agency does not require similar labeling statements for such products. The comment contended that requiring an anticavity dental rinse/mouthwash product to display the ''not a mouthwash'' labeling statement is inconsistent with agency policy for these other OTC products and could be confusing to consumers who have been receiving both benefits from previous use of these products.

The comment argued that the agency's proposal would adversely affect the truthful promotion of OTC anticavity dental rinses, and that consumers desiring both anticavity and breath freshening activity would have to purchase two separate products (i.e., an anticavity dental rinse and a cosmetic mouthwash) instead of purchasing one product that would provide both benefits. The comment requested the agency to delete the statement in proposed § 355.50(e)(2) that says ''This is a(n)'' (select one or both of the following: ''anticavity'' or ''fluoride'') ''treatment rinse, not a mouthwash.''

In the tentative final monograph for OTC anticaries drug products, the agency expressed concern that, because fluoride dental rinses and cosmetic mouthwashes are similar in appearance, consumers might confuse such products (50 FR 39854 at 39869). The agency stated that proper labeling is an important aid to preventing consumer confusion as to the use of these products. Therefore, the agency proposed labeling, including the labeling statement ''* * * not a mouthwash * * *'' in § 355.50(e)(2), to minimize confusion and to help consumers distinguish between dental rinses and cosmetic mouthwashes.

The agency sees no reason why an appropriately labeled OTC fluoride rinse cannot also be used for freshening the breath. Such a product can properly be identified as an anticavity or fluoride rinse or mouthwash (see section I.C., comment 18 of this document). However, the agency believes that proper labeling of OTC fluoride rinses is an important factor in helping to ensure the safe and effective use of these products.

The agency is concerned that, based upon familiarity with cosmetic mouthwash use, a consumer might overuse and/or misuse an OTC fluoride rinse. For example, directions for use of fluoride rinses are notably different from directions for use of cosmetic mouthwashes. Cosmetic mouthwashes are often labeled for multiple use during the day (e.g., ''first thing in the morning, after meals, and before social engagements'') (Ref. 1). Fluoride rinses are labeled for use once or twice a day (§ 355.50(d)(2)). Cosmetic mouthwash labeling directs consumers to ''rinse or gargle 30 seconds'' (Ref. 1). The directions for use of fluoride rinses state that consumers should ''* * * swish * * * between your teeth for 1 minute * * * Do not eat or drink for 30 minutes after rinsing'' (§ 355.50(d)(2)).

Based on the above discussion, the agency has determined that the ''not a mouthwash'' statement need not be required labeling for OTC fluoride rinses. Accordingly, the agency is not including proposed § 355.50(e)(2) in this final monograph. However, in order to maximize the safe and effective use of OTC fluoride rinses, the agency concludes that these products must contain labeling that clearly instructs consumers to read the directions. The agency also believes that this information should be displayed on the principal display panel. Therefore, the agency is including in this final monograph new § 355.55 as follows: ''*Principal display panel of all fluoride rinse drug products*. In addition to the statement of identity required in § 355.50, the following statement shall be prominently placed on the principal display panel: 'IMPORTANT: Read directions for proper use'.''

Reference

(1) Labeling for Scope®, OTC Vol. 08AFM, Docket No. 80N–0042, Dockets Management Branch.

21. One comment disagreed that the heading ''Indication'' proposed in § 355.50(b) was needed in the labeling of OTC fluoride dentifrice products. The comment contended that the function of a fluoride toothpaste is generally known, and consumers have safely and correctly used these products for years without the heading ''Indication'' in the labeling of these products. The comment added that the consuming public probably does not consider fluoride toothpaste to be a drug in the same sense as other common OTC drug products; thus, consumers could be confused by this new labeling requirement. The comment suggested that § 355.50(b) be revised to make use of the heading ''Indication'' optional.

The agency does not agree that the heading ''Indication(s)'' should be optional. All OTC drug monographs in parts 331 through 358 (21 CFR 331 through 358) have been promulgated with a standard ''Indications'' paragraph requiring that the labeling of the product state its FDA approved use(s) under the heading ''Indication(s).'' However, two general OTC drug product labeling provisions, which were promulgated after the comment was submitted, provide alternatives. Section 330.1(c)(2)(i) provides that, at the option of the manufacturer, the ''Indications'' may be designated ''APPROVED USES'' or given a similar designation as permitted in that paragraph of the regulations. Section 330.1(i)(8) provides that ''indications'' or ''uses'' may be used interchangeably.

Although the comment claims that consumers may not be accustomed to reading such information on dentifrice product labels, the agency believes that consumers should be aware that these products are drugs. This same principle would apply to other OTC products that consumers might not consider to be drugs because they have not contained such labeling in the past, e.g., antiperspirants and sunscreens. The comment did not provide any evidence that consumers would be confused by

reading this type of labeling, which has appeared for years on many widely used OTC drug products. The agency finds that informative headings such as ''Indications'' or ''Uses'' (as well as ''Warnings'' and ''Directions'') are useful to consumers and provide uniformity to OTC drug product labeling. Therefore, the agency is not making use of the heading ''Indication(s)'' optional.

22. One comment noted that § 330.1(g) (21 CFR 330.1(g)) requires that all drugs, unless exempted, be labeled with the warning ''Keep this and all drugs out of the reach of children.'' The comment stated that OTC anticaries dentifrices and rinses obviously should not be subject to the general warning because they bear directions for use by children. The comment requested that OTC anticaries drug products be exempted from the requirement to bear this warning.

The agency agrees, in part, with the comment. The agency recognizes that fluoride dentifrices are generally kept within the reach of children to encourage use on a regular basis. The agency is concerned that the general warning ''Keep this and all drugs out of the reach of children'' could discourage or inhibit parents from keeping fluoride dentifrices within easy reach of children 6 years of age and older who are able to use dentifrice products safely and effectively. However, these products should not be within easy reach of children under 6 years of age, who should be supervised and instructed in the proper use of these products and who are vulnerable to dental fluorosis. Thus, in § 355.50(c) of this final monograph, the agency is modifying the § 330.1(g) warning to read as follows for fluoride dentifrice products: ''Keep out of the reach of children under 6 years of age.''

The agency disagrees with the comment with respect to fluoride rinses and gels. The agency believes that these dosage forms should not be within easy reach of any children. These products are not indicated for use in children under 6 years of age on an OTC basis. For children 6 to under 12 years of age, the products must be labeled for use under the supervision of an adult. These fluoride dosage forms are potentially more toxic than fluoride dentifrice products because they do not contain an abrasive that can bind some the fluoride ion and because a child under 6 is more likely to drink a flavored liquid than eat large amounts of toothpaste, which may contain up to 40 percent by weight of inert abrasive ingredients.

The agency has reviewed its adverse reaction data base covering the period from 1985 to 1992 for reports related to fluoride rinses, gels, and dentifrices (Ref. 1). In the 0- to 9-year age group, there were 22 reports for fluoride rinses and gels, but no reports for fluoride dentifrice products. In addition, the agency has reviewed available data concerning exposures to fluoride toothpastes and fluoride rinses (mouthwash) in annual reports of the American Association of Poison Control Centers for the years 1989 to 1991 (Refs. 2, 3, and 4). For children under 6 years of age, the number of accidental exposures averaged approximately 1,200 per year for fluoride toothpastes and almost 1,000 per year for fluoride rinses. However, fluoride toothpaste usage is estimated to be 300 times that of fluoride rinses. Thus, the accidental ingestion rate for fluoride toothpaste is much lower than for fluoride liquid products. Therefore, the available data strongly support a requirement that fluoride rinses and gels be labeled in accord with the general warning in § 330.1(g), without any modifications. This requirement appears in § 355.50(c)(2) of this final monograph.

References

(1) Food and Drug Administration, Center for Drug Evaluation and Research, Adverse Reaction Summary Listing for Fluoride Rinses, Gels, and Dentifrices for years 1985 to 1992, OTC Vol. O8AFM, Docket No. 80N–0042, Dockets Management Branch.

(2) Litovitz, T. L. et al., ''1989 Annual Report of the American Association of Poison Control Centers National Data Collection System,'' *The American Journal of Emergency Medicine*, 8:421, 1990.

(3) Litovitz, T. L. et al., ''1990 Annual Report of the American Association of Poison Control Centers National Data Collection System,'' *The American Journal of Emergency Medicine*, 9:488, 1991.

(4) Litovitz, T. L. et al., ''1991 Annual Report of the American Association of Poison Control Centers National Data Collection System,'' *The American Journal of Emergency Medicine*, 10:480, 1992.

23. Two comments disagreed with the directions proposed in § 355.50(d)(1) for anticaries dentifrices, which state: ''Adults and children 2 years of age and older: brush teeth thoroughly at least once daily or as directed by a dentist or doctor. Children under 6 years of age should be supervised in the use of this product.'' The comments disagreed in two major areas: (1) The agency's reference to brushing at least once daily may be misinterpreted by the public as being adequate and, therefore, may lead to less brushing and poor oral health care. The comments indicated that there is no clear consensus within the dental profession as to the number of times teeth should be brushed each day. Many dentists recommend brushing after each meal, and, for reasons of practicality, brushing at least twice a day—after breakfast and in the evening. The comments indicated that they are unaware of any data that suggest brushing once a day is adequate, and therefore urged the agency not to refer to any minimum number of times for brushing. (2) The contraindication for the use of fluoride dentifrices by children under 2 years of age is unwarranted because children that age have many teeth requiring anticaries protection. The comments stated that early instruction of children regarding dental care minimizes the risk of fluorosis due to ingestion of fluoride dentifrice and encourages good oral health care habits.

The Panel reviewed several clinical studies that showed fluoride-containing dentifrices effectively increase resistance to enamel solubility and therefore reduce dental decay when applied to the teeth at least once a day (Refs. 1, 2, and 3). Radike (Ref. 3) describes three 1-year clinical studies with a similar design conducted to determine whether the frequency of application affects the anticariogenic effect of a stannous fluoride dentifrice. Each study used similar stannous fluoride dentifrices, but the subjects (school children) were assigned one of three different brushing procedures: (1) Unsupervised brushing, (2) supervised brushing once-a-day after the noon meal, and (3) supervised brushing three times a day (after breakfast and dinner and before retiring). Each brushing regimen was assigned approximately the same number of control subjects as test subjects. Subjects in a control group assigned to a specific brushing procedure brushed with a nonfluoride-containing dentifrice. In the study in which no toothbrushing instructions were given and the subjects were allowed to follow their usual brushing habits, the fluoride dentifrice subjects developed 23 percent fewer new caries than those in the control group. In the study with one supervised brushing in the school room after the noon meal, the fluoride dentifrice subjects developed 34 percent fewer caries than those in the control group. In the third study with supervised brushing three times a day (after breakfast and dinner and before retiring), the fluoride dentifrice subjects developed 57 percent fewer new caries than those in the control group. The results from these studies clearly suggest that simply cleansing the teeth with an abrasive containing nonfluoridated dentifrice is not as effective in reducing the incidence of caries as brushing with a fluoride-

containing dentifrice. The data also show that more frequent topical applications of fluoride significantly enhance anticaries protection. Supervised brushing with a fluoride dentifrice once-a-day after the noon meal resulted in 33 percent fewer cavities than unsupervised brushing. Further, subjects who brushed three times a day with a fluoride dentifrice experienced: (1) 40 percent fewer new cavities than those who brushed with a fluoride dentifrice only once-a-day, even under supervision, and (2) 60 percent fewer cavities than those whose brushing was unsupervised. The results of these three studies indicate that fewer caries occur as frequency of supervised brushing and brushing after meals is increased.

Several additional studies (Refs. 4 through 7) also indicate that brushing immediately after meals is the most favorable time to reduce the number of cariogenic bacteria from all tooth surfaces. Two review studies (Refs. 4 and 6) discussed the role nutrition plays in the etiology of dental disease. Both studies concluded that one preventative measure to effectively reduce the number of cariogenic bacteria present in the mouth is to brush thoroughly after each meal with a fluoride-containing dentifrice. Forty years ago, another study (Ref. 7) indicated that many dentists and health workers strongly recommend that toothbrushing be performed immediately after the ingestion of sugar-containing food if brushing is to be effective in reducing dental cavities. The study also included a clinical investigation evaluating the effectiveness of reducing dental cavities by brushing the teeth with one of three types of nonfluoridated dentifrices immediately after the ingestion of food. This report (Ref. 7) dealt with only one of the dentifrices, the neutral paste. Subjects in the experimental group were instructed individually to brush their teeth thoroughly within 10 minutes after each ingestion of food or sweets and, when brushing was not possible, to rinse the mouth thoroughly with water. Toothbrushes and dentifrice were supplied to all experimental subjects. Subjects in the control group were not supplied with dentifrices or brushes, but were instructed to continue their customary oral hygiene habits of brushing only on arising and before retiring, rather than after the ingestion of food. When this study was conducted in 1950, fluoridated toothpastes were not available in the marketplace; thus, the control subjects would not have used a fluoridated dentifrice as a part of their customary oral hygiene habits. Clinical results after 1 year indicated that brushing thoroughly immediately after the ingestion of food resulted in a 63-percent reduction in caries activity in the experimental group when compared to the control group.

A more recent 1982 study (Ref. 8) reviewed the prevention control of oral diseases and recommended at least two daily brushings with a fluoride dentifrice as effective in reducing the incidence of dental cavities. The study further stated that because toothbrushing is intended to remove food debris and dental plaque from the teeth, brushing after meals and sweet snacks is commonly recommended in dental health messages to the public.

The agency agrees with the comments and with many dentists that brushing properly and thoroughly more often than once daily will promote better oral health care. Reducing cariogenic activity by brushing more often than once a day, particularly after meals, can be explained by the synergistic effect of the antienzymatic properties of fluoride (45 FR 20666 at 20672) along with the mechanical removal of food debris. The Panel recognized that three factors are necessary for caries to occur (45 FR 20666 at 20672): (1) The teeth must be susceptible to caries, (2) acid-producing bacteria of the mouth must colonize on the teeth, and (3) a substrate must be present for bacteria to proliferate and to produce acid for demineralization of the teeth. Effective anticaries protection is achieved by exposing the tooth enamel to fluoride ions and by the mechanical removal of dental plaque and food debris from tooth surfaces and gingival tissue areas. Both objectives are better accomplished by toothbrushing more often than once daily, preferably after meals. The mechanical removal of food debris from teeth and gingival areas decreases the availability of metabolized carbohydrate sources, which are required for caries development.

The agency agrees with the Panel that brushing with a fluoride-containing dentifrice at least once daily effectively renders the teeth less susceptible to dental cavities. The agency also recognizes, however, that anticaries protection could be enhanced by brushing more than once a day, preferably after each meal to remove the food particles that provide the substrate necessary for bacteria to proliferate and produce acid in the development of dental caries (Ref. 3). Therefore, the agency is revising part of the directions for all OTC fluoride dentifrices to read: ''* * * brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.''

The agency disagrees with the comments suggesting that the contraindication for children under 2 years of age is unwarranted. Very young children cannot be expected to rationally interpret and consistently follow the instructions involving proper toothbrushing; nor do they have the manual dexterity to use the fluoride dentifrice product properly. Children under 2 years of age do not have control of their swallowing reflex and do not have the skills to expectorate the toothpaste properly (50 FR 39854 at 39867). Although the prevalence of dental caries is decreasing, some reports suggest the incidence of mild fluorosis (a permanent, mottled discoloration of the teeth) in young children is increasing in the United States due to the increase of fluoride in our food chain (Ref. 9). Excessive ingestion of fluoride by young children increases the risk of fluorosis during the critical time of anterior teeth development and can interfere with the successful development of other emerging teeth (Ref. 10). Toothbrushing for children under 2 years of age when teeth are first emerging may also cause minor injury to the soft tissue in the mouth. The agency recognizes that young children are most susceptible to mild fluorosis as a result of improper use and swallowing of a fluoride dentifrice product. Based on the above, the agency concludes that it is appropriate to include in the labeling of fluoride dentifrice drug products containing 1,000 ppm theoretical total fluorine the following sentence: ''Children under 2 years of age: Consult a dentist or doctor.'' The agency is including this sentence in the directions in § 355.50(d)(1)(i) of this final monograph. The agency is also including a similar statement in the directions for dentifrices containing 1,500 ppm theoretical total fluorine for children under 6 years of age (see section I.B., comment 10 of this document).

References

(1) Council on Dental Therapeutics, *Accepted Dental Therapeutics*, 37th ed., American Dental Association, Chicago, p. 303, 1977.

(2) Council on Dental Therapeutics, ''Evaluation of Super Stripe Toothpaste,'' *Journal of the American Dental Association*, 71:930–931, 1966.

(3) Radike, A. W., ''Current Status of Research on the Use of a Stannous Fluoride Dentifrice,'' in OTC Vol. 080099.

(4) Massler, M., ''Nutrition and Dental Decay,'' *Food and Nutrition News*, 39:1–4, 1968.

(5) Nikiforuk, G., and J. B. MacDonald, ''An Evaluation of Dentifrices in the Prevention of Dental Caries and Gingivitis,'' *Journal of the*

Canadian Dental Association, 21:557–565, 1955, Abstracted in *Dental Abstracts*, 1(4):227, 1956.

(6) Finn, S. B., and R. B. Glass, ''Sugar and Dental Decay,'' *World Review of Nutrition and Dietetics*, 22:318–320, 1975.

(7) Fosdick, L. S., ''The Reduction of the Incidence of Dental Caries. 1. Immediate Tooth-Brushing with a Neutral Dentifrice,'' *The Journal of the American Dental Association*, 40(2):133–143, 1950.

(8) Council on Dental Therapeutics, *Accepted Dental Therapeutics*, 39th ed., American Dental Association, Chicago, pp. 335–337, 1982.

(9) Leverett, D. H., ''Fluorides and the Changing Prevalence of Dental Caries,'' *Science*, 217:26–30, 1982.

(10) Simard, P. L. et al., ''The Ingestion of Fluoride by Young Children,'' *Journal of Dentistry for Children*, 56:177–181, 1989.

24. Three comments objected to the directions proposed in § 355.50(d)(1) for anticaries products marketed in a dentifrice dosage form (containing 1,000 ppm theoretical total fluorine), which states: ''Children under 6 years of age should be supervised in the use of this product.'' The comments contended that this is the type of language that is customarily used for products or activities that are dangerous, thus the language is needlessly alarmist. The comments explained that ''supervision'' in this usage connotes watchfulness to prevent any action by the child that could lead to harm. The comments claimed that a parent reading this direction for use might infer that toothpaste has some dangerous hidden toxicity. The comments emphasized that the important point is that children should be trained how to brush their teeth so that they will obtain the desired benefit of toothbrushing without swallowing excessive amounts of toothpaste, which would increase their risk of fluorosis. One comment stated that the proposed labeling implies that even after good brushing habits are acquired, every toothbrushing event until age 6 should be supervised by a parent. The comments requested that the directions be revised to read: ''Instruct children under 6 years of age in good brushing and rinsing habits as recommended by your dentist.'' The comments argued that implicit in the concept of instruction is supervision until the parent is satisfied that the child can follow the instruction correctly. The comments concluded that the term ''instruction'' rather than ''supervision'' provides the correct emphasis, provides useful guidance adequate to deal with the concern about fluorosis, and does so without stimulating unwarranted parental concern.

Another comment did not object to the term ''supervised'' in the direction for dentifrices containing 1,000 ppm theoretical total fluorine, but requested the agency to expand § 355.50(d)(1) to read: ''To prevent swallowing, children under 6 years of age should be supervised in the use of toothpaste (mouthrinse).'' The comment stated that young children should be educated in the proper manner of toothbrushing so as to help enhance proper brushing technique as well as appropriate product use (i.e., using small portions and spitting the dentifrice out after use, rather than ingestion). The comment stated that the Council on Dental Therapeutics of the American Dental Association (ADA) has recently adopted this statement and directed its use on all labeling for Council-accepted fluoride-containing dentifrices and mouthwashes.

The agency agrees with the comments. The Panel recommended that fluoride dentifrices be labeled to indicate that children under 6 years of age should be supervised in the use of these products. In the tentative final monograph for OTC anticaries drug products (50 FR 39854 at 39867), the agency interpreted the Panel's statement to mean that all children under 6 years of age should be properly instructed and supervised in the use of a dentifrice, but the amount of supervision may vary depending on a child's skills. If a child has fairly good toothbrushing skills, parents may allow unsupervised brushing, but may wish to check the child's toothbrushing techniques periodically. The agency did not intend that every toothbrushing event until age 6 should be supervised. As the comments suggested, the important point is for parents to assure themselves that their children are learning the proper use of dentifrices, and once they are assured of this, supervision is no longer required. The agency agrees that the labeling should make this point without being unnecessarily overcautious or alarmist.

Regarding the request to expand § 355.50(d)(1) to include the language ''To prevent swallowing * * * ,'' the agency agrees that the objective of instruction and supervision is to avoid excessive ingestion of the dentifrice. However, the agency believes that the word ''prevent'' may be too strong a term and that prevention of some swallowing of dentifrices is unachievable in young children. The amount of dentifrice ingested varies with the age and skill of the child. The Panel reviewed a study (Ref. 1) involving children 2 to 6 years of age that showed large individual variations in expectorated volumes after mouthrinsing with water. Only a few of the children between 2 and 3 years of age could perform mouthrinsing without swallowing the fluid. The 3- and 4-year-old children could, as a rule, keep the fluid in their mouths for 30 seconds. The 5- and 6-year-old children could all perform the rinse for 1 minute; these children had considerably less individual variation in expectorated volumes. Based on these data, the agency finds that suggesting to parents that swallowing can be prevented may cause unnecessary alarm when they observe a young child swallow small amounts of dentifrice during the learning process. Accordingly, the agency is using the word ''minimize'' instead of ''prevent'' in this final monograph. The revised direction statement in § 355.50(d)(1)(i) reads: ''Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.''

Reference

(1) Ericsson, Y., and B. Forsman, ''Fluoride Retained from Mouthrinses and Dentifrices in Preschool Children,'' *Caries Research*, 3:290–299, 1969.

25. One comment objected to the part of the proposed directions in § 355.50(d)(2)(i) for anticaries products marketed for use as treatment rinses, which states: ''Children under 12 years of age should be supervised in the use of this product.'' The comment stated that the Panel recommended that children under 6 years of age be supervised in the use of fluoride dentifrices (45 FR 20666 at 20673), but did not mention children above 6 years of age. The comment suggested that the Panel's recommendation was made in order to limit daily fluoride ingestion and thereby avoid possible dental fluorosis. The comment cited the Panel's discussion of epidemiological and clinical findings that indicated that teeth of children 6 years of age and older are ''(excepting third molars) * * * too advanced to be affected by excessive daily fluoride ingestion.'' The comment mentioned the Panel's discussion (45 FR 20666 at 20673) that children 6 years of age and older have developed control of their swallowing reflexes and are able to rinse for 1 minute and expectorate properly. The comment stated that if the agency is concerned that children between 6 and 12 years of age using the product for the first time may not be able to follow label directions without instruction from a parent or other adult, then limited directions about supervision might be useful. However, the comment expressed concern that continuing

supervision each time the product is used did not appear warranted and that this unnecessarily overcautious labeling could discourage use of these products.

The agency agrees. As discussed in comment 24, the agency interpreted the Panel's statement to mean that children under 6 years of age should be properly instructed and supervised in the use of a dentifrice, not because of any particular hazard, but to ensure that the child is developing adequate toothbrushing skills and is using the product correctly. Instruction and supervision serve the same purpose for fluoride rinses (i.e., to assure proper use of these products) and are not intended to discourage use of fluoride rinses by children. Once the parent is certain that the child is using the product correctly, unsupervised use may be allowed. Therefore, the agency is revising part of the directions statement to read: ''Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.''

26. One comment disagreed with the agency's proposal to include the following statement in § 355.50(c) as a warning for concentrated treatment rinse solutions, powders, and effervescent tablets: ''Do not use before mixing with water. Read the directions carefully.'' The comment stated that neither the Panel in the advance notice of proposed rulemaking (45 FR 20666) nor the agency in the tentative final monograph for OTC anticaries drug products identified a compelling safety hazard that warrants including the information in the warnings section rather than in the directions for use. The comment contended that the safe use of these concentrated products is amply ensured by including the quoted language in the directions for use. The comment requested that this information be included in the directions section only, because it concerns proper use of a product rather than cautioning to prevent possible dangers of misuse.

In the tentative final monograph, the agency stated that, in order to alert consumers that dental rinse products in concentrated form (solutions, powders, and effervescent tablets) must be diluted or dissolved in water before using, the agency is proposing the warning stated above for these dosage forms. The agency agrees with the comment that consumers could equally be alerted if this information appeared in the directions for use section. Accordingly, in this final monograph, the agency is moving the statement ''Do not use before mixing with water.'' from the warnings to the directions for use section. This statement is to appear as the first statement under the directions for use for concentrated treatment rinse solutions, powders, and effervescent tablets. It should then be followed by the proper directions for preparing the diluted rinse product. The part of the proposed warning that stated ''Read the directions carefully.'' is not needed when this revised labeling format is used.

27. Several comments objected to the agency's proposed labeling statement in § 355.50(e)(3) for OTC stannous fluoride-containing dentifrices, treatment gels, and treatment rinses, which states: ''This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.'' In support of their objections to this statement, one comment cited five published studies (Refs. 1 through 5) and another comment submitted an unpublished study of the incidence of stained teeth in school children who used a stannous fluoride dentifrice (Ref. 6). Stating that the evidence regarding the propensity of stannous fluoride products to stain teeth is equivocal, another comment argued that the labeling statement should be required only on those stannous fluoride products that have been scientifically proven to cause substantial and discernible staining on the teeth of users. The comment urged the agency to abandon or strictly limit its proposal to require a teeth staining labeling statement on OTC stannous fluoride dentifrice products.

Three comments noted that the Panel specifically stated in its discussion of stannous fluoride dentifrice drug products (45 FR 20666 at 20685) that ''* * * the frequency and intensity of staining with the level of tin present in these formulations does not appear to present any significant problem; therefore, no labeling statement on staining shall be required for stannous fluoride dentifrice formulations * * *.'' Two of the comments stated that the agency failed to offer any new evidence that would make the findings of the expert panel inappropriate. One of the comments asserted that all the studies cited by the agency in support of the proposed labeling statement for stannous fluoride dentifrice products (50 FR 39854 at 39865 and 39866) were cited previously by the Panel as support for its conclusion that no labeling statement about tooth staining was necessary (45 FR 20666 at 20685). Another comment mentioned extensive experience with the first stannous fluoride dentifrice formulation marketed in the United States. This comment stated that no incidence of surface staining was found that would justify such a labeling statement.

One comment suggested that the tendency of stannous fluoride products to cause staining of the teeth is directly related to a number of factors. It may be highly dependent on the formulation of the product and/or the brushing habits of the user. The comment stated that the stability of the fluoride and the stannous ions in a product have an effect on whether or not the product causes tooth staining. For example, a product that contains a high level of stannous ions may be more likely to stain teeth than a product that is stabilized and, therefore, does not contain many stannous ions. The comment asserted that stable stannous fluoride products (e.g., dental gels) are not likely to cause discernible staining. The comment concluded that the labeling statement about tooth staining should not be imposed indiscriminately on all stannous fluoride products without regard to the stability of the product.

One comment contended that requiring the labeling statement about tooth staining on stannous fluoride dentifrice products would cause undue concern among consumers. The comment was concerned that the proposed warning would cause users to avoid safe and effective stannous fluoride products in favor of other products that do not bear such a warning. Another comment stated that requiring such a labeling statement without reliable scientific support is damaging to consumers who may place undue emphasis on the possibility of some transient staining. The first comment added that requiring the labeling statement regardless of whether or not a product caused staining of the teeth would handicap stannous fluoride products that could be shown not to cause a greater amount of staining than any other fluoride product.

Another comment contended that the data used by the agency to support the tooth staining labeling statement (50 FR 39854 at 39865 and 39866) are flawed and do not support the agency's decision to require this statement on stannous fluoride products. Stating that none of the studies attempted to relate the incidence of staining to any element of the dentifrice other than stannous fluoride, the comment asserted that interaction between the polishing agent (abrasive) and the fluoride moiety may be responsible for any staining observed. The comment noted that the polishing agent in the stannous fluoride dentifrices in some studies was sodium

metaphosphate. The comment maintained that it is impossible to know whether similar results would have occurred if a different polishing agent had been used. The comment concluded that these data show that stannous fluoride contained in a dentifrice base of sodium metaphosphate can cause mild staining in some subjects when analyzed by investigators in blind, controlled settings.

The comment added that the studies used by the agency to support the proposed staining statement (50 FR 39854 at 39865 and 39866) did not compare the reported incidence of tooth staining with consumer perception of such staining. The comment maintained that these studies demonstrate that tooth staining caused by stannous fluoride products is barely perceptible by consumers and is of little importance to the vast majority of people under normal conditions of daily use. The comment and another comment mentioned a study by Ness, Rosekrans, and Welford (Ref. 5) that also demonstrates that staining is barely perceptible and not important to consumers.

One comment agreed with the Panel that a labeling statement about tooth staining is unnecessary for stannous fluoride dentifrices. However, the comment asserted that, if the agency determines that such a labeling statement is necessary, the data support only a limited labeling statement for stannous fluoride dentifrice products in which sodium metaphosphate is the polishing agent. In addition, the comment requested that this labeling statement be modified to reflect the underlying data as follows: ''This product may occasionally produce minor temporary surface staining of teeth. Adequate toothbrushing will prevent these stains and they may be easily removed by your dentist.''

The agency does not believe that the studies submitted by the comments support eliminating the labeling statement regarding tooth staining from stannous fluoride dentifrice products. Although two of the six studies submitted do not show significant staining caused by stannous fluoride dentifrice products (Refs. 5 and 6), four of the six studies (Refs. 1 through 4) demonstrate that test groups using stannous fluoride dentifrice products had significantly more tooth staining than groups using dentifrice products without fluoride. Three of these studies (Refs. 1, 2, and 4) used a dentifrice with calcium pyrophosphate as the abrasive agent. Sodium metaphosphate was the abrasive agent used in the other study (Ref. 3). These studies do not indicate that tooth staining is related to any individual polishing agent. However, based on the information available from the studies, the agency is unable to determine if staining is a formulation specific problem. The agency believes that the information submitted clearly demonstrates that stannous fluoride dental products (i.e., dentifrices, nses, and gels) have the potential to produce surface staining of the teeth. The agency is not aware that such staining results from the use of any other commonly utilized fluoride ingredients.

The agency reaffirms its conclusion that a labeling statement regarding tooth staining should be required on all stannous fluoride products. The agency believes that: (1) Consumers should be advised that staining of the teeth may be caused by stannous fluoride products, including dentifrices, and (2) that adequate brushing or dental prophylaxis may prevent the stains. The agency does not believe that one comment's suggested labeling statement about tooth staining has any advantage over the statement proposed by the agency in the tentative final monograph. The comment's suggested statement uses words like ''occasionally'' and ''minor'' and is more ambiguous than the agency's proposed statement. The agency's statement conveys a more meaningful message using the phrase ''may produce surface staining.'' In addition, the agency's statement advises the consumer that the staining is not harmful or permanent. The agency considers its proposed statement to be more informative than the comment's suggested statement and more helpful to consumers. Therefore, the agency is including its proposed labeling statement in § 355.50(e)(2) of this final monograph.

References

(1) Jackson, D., and P. Sutcliffe, ''Clinical Testing of a Stannous Fluoride-Calcium Pyrophosphate Dentifrice in Yorkshire School Children,'' *British Dental Journal*, 123:40–48, 1967.

(2) James, P. M. C., and R. J. Anderson, ''Clinical Testing of a Stannous Fluoride-Calcium Pyrophosphate Dentifrice in Buckinghamshire School Children,'' *British Dental Journal*, 123:33–39, 1967.

(3) Naylor, M. N., and R. D. Emslie, ''Clinical Testing of Stannous Fluoride and Sodium Monofluorophosphate Dentifrices in London School Children,'' *British Dental Journal*, 123:17–23, 1967.

(4) Slack, G. L. et al., ''Clinical Testing of a Stannous Fluoride-Calcium Pyrophosphate Dentifrice in Essex School Girls,'' *British Dental Journal*, 123:26–33, 1967.

(5) Ness, L., D. L. Rosekrans, and J. F. Welford, ''An Epidemiological Study of Factors Affecting Extrinsic Staining of Teeth in an English Population,'' *Community Dentistry and Oral Epidemiology*, 5:55–60, 1977.

(6) Katayama, T., ''Incidence of Stained Teeth on School Children Who Have Used Stabilized SnF_2 Toothpaste for Three Years,'' unpublished study in Comment No. C63, Docket No. 80N–0042, Dockets Management Branch.

28. One comment requested that the professional labeling in § 355.60 be modified to require that only dental rinse formulations composed of ingredients suitable for swallowing be used as fluoride supplements intended for ingestion in areas where the water supply is nonfluoridated. The comment stated that this section, as proposed, does not mention that fluoride rinses promoted to health professionals and not offered to the general public are specially formulated with ingredients suitable for ingestion. These products are intended to be swallowed. The comment mentioned that dental rinse products not intended to be swallowed are formulated differently and contain other ingredients.

The agency agrees that further explanation of the term ''supplement'' would help to reduce possible confusion. Therefore, the agency is modifying the introductory language in the professional labeling in § 355.60 as follows: ''The labeling for anticaries fluoride treatment rinses identified in § 55.10 that are specially formulated so they may be swallowed (fluoride supplements) and are provided to health professionals (but not to the general public) may contain the following additional dosage information: * * *.'' Also, the agency is including a definition of fluoride supplement in § 355.3 as follows: ''Fluoride supplement. A special treatment rinse dosage form that is intended to be swallowed, and is promoted to health professionals for use in areas where the water supply contains 0 to 0.7 parts per million fluoride ion.''

D. Comments on the Switch of Prescription Anticaries Drug Products to OTC Status

29. One comment objected to the proposed prescription-to-OTC switch of 0.4 percent stannous fluoride gel products for economic and labeling reasons. The comment indicated that currently only small manufacturers make and market these products on a prescription basis. The comment asserted that OTC status would disadvantage these small companies by forcing them into the OTC marketplace with obvious competitive and marketing expenses. According to the comment, promoting its products through health-care professionals is less costly than promoting the products to the general

public on an OTC basis. The comment contended that OTC status creates a labeling problem that does not exist when these products are marketed as prescription drugs. The comment identified this problem as a''negative statement'' required in the product's labeling, i.e., ''not a toothpaste.'' The comment concluded by suggesting that the interests of the consuming public and ''small'' entities are best served by not including 0.4 percent stannous fluoride gel in the OTC drug monograph and by continuing its prescription status.

The agency does not agree with the comment. The Panel recommended that certain fluoride dental rinses and gels, which had previously been restricted to prescription use, be made available OTC provided that they conform to package size limitations and proper labeling to avoid misuse (45 FR 20666 at 20666, 20674, and 20691). (Package size limitations are discussed in section I.G., comment 46.) The Panel reviewed four published studies on stannous fluoride dental gels containing 0.4 percent stannous fluoride in an anhydrous glycerin gel (45 FR 20682) and concluded that these studies provide sufficient documentation of the safety and effectiveness of this dental gel dosage form for OTC use. In the tentative final monograph (50 FR 39854 at 39858), the agency concurred with the Panel's recommendation that 0.4 percent stannous fluoride in an anhydrous glycerin gel be switched to OTC status and labeled with proper directions for use (45 FR 20688).

The agency is aware that the change of 0.4 percent stannous fluoride dental gels from prescription-to-OTC status will lead to different marketing strategies and promotional activities. However, the agency has determined that such a product can be generally recognized as safe and effective and marketed as an OTC product. This OTC status does not prevent a manufacturer from continuing to promote the use of such products through health-care professionals, who then would instruct their patients to purchase and use the products.

In response to the comment's objection to the proposed labeling of its product with the statement ''This is not a toothpaste,'' the agency indicated in the tentative final monograph (50 FR 39869) that a nonabrasive dental gel packaged in a conventional tube can be confused with a conventional abrasive-containing dentifrice. There is also a safety concern because dentifrices contain an abrasive, while these dental gels do not. This safety concern is discussed in section I.G., comment 46 of this document. The agency considers the statement for dental gel products to be important to their safe OTC use.

The agency concludes that the OTC availability of 0.4 percent stannous fluoride dental gel products provides benefit to consumers and poses very little risk of misuse when the products are packaged and labeled properly. Therefore, the agency is including 0.4 percent stannous fluoride dental gel products in this final monograph.

30. One comment objected to the 120-mg package size limitation for fluoride treatment gels proposed in § 55.20. The comment requested that a 7-ounce (oz) package size for 0.4 percent stannous fluoride preventive treatment gels (containing 192 mg total fluorine) remain in the marketplace, at least as a prescription drug product for use under the supervision and direction of the dental profession. The comment noted that its decision to market a 7-oz package size of 0.4 percent stannous fluoride treatment gel was partially based on the 7-oz package size of 0.4 percent stannous fluoride dentifrice products marketed at the time its product was introduced into the marketplace. The comment noted that, in the tentative final monograph (50 FR 39854 at 39857), the agency cited the position and experience since 1958 of the ADA concerning package size limitations for OTC rinses and gels in support of the proposal in § 355.20 to limit package sizes for dental rinses and gels.

The comment mentioned over 10 years of safe prescription marketing of its 7-oz product with a child-proof safety closure. The comment contended that consumer use is different with regard to the safe handling of prescription drug products, as compared to OTC drug products. The comment noted that the agency concluded in the tentative final monograph that a toxic dose of fluorine via a dentifrice drug product could not be ingested without vomiting, although the agency did not address the effect of glycerin (which is used in the treatment gel) with regard to vomiting. The comment stated that the 7-oz package size of this product represents over 50 percent of its dollar volume and its discontinuance would represent a hardship. The comment requested reconsideration of the OTC status of the 7-oz package size for its 0.4-percent stannous fluoride treatment gel. The comment stated that, at a minimum, allowing this product to remain in the marketplace on a prescription basis would best serve the interests of the dental profession and small businesses in the stannous fluoride industry without endangering public safety.

In the tentative final monograph (50 FR 39854 at 39857), the agency concurred with the Panel's recommendation that the package size of OTC preventive treatment gel products be limited to 120 mg total fluorine because of possible safety concerns. The Panel was concerned about the significant differences in the amount of fluorine available for pharmacological or toxicological action between dentifrices (abrasive-containing) and nonabrasive treatment gels and rinses. Available fluoride in a dentifrice is dependent upon the chemical reactivity of the fluoride ion with the abrasive (45 FR 20675 to 20677), while all of the fluoride ion in the nonabrasive preventive treatment gel is available. There are potential safety concerns (i.e., ingestion of an entire package that could cause serious effects, particularly for a small child) when the 120-mg total fluorine package size limitation for a preventive treatment gel is exceeded. This package size limitation appears in § 355.20 of this final monograph. Although the package size will vary depending on the concentration of the fluoride ingredient in the product, the maximum OTC package size of a 0.4-percent stannous fluoride preventive treatment gel product is 4.375 oz. The agency has no objection to larger size packages being available as prescription drug products. However, if a manufacturer wishes to market a 0.4-percent stannous fluoride preventive treatment gel product in a larger package size on a prescription basis, the manufacturer must obtain an approved NDA under section 505 of the act (21 U.S.C. 355) and part 314 of the regulations.

The comment provided no data or information in support of its contention that the general public handles prescription drugs differently than OTC drugs. The agency believes that more potent prescription drug products generally are handled differently than most OTC drugs. However, the agency is unaware of any data that suggest that consumers handle prescription anticaries gels and treatment rinses differently than OTC anticaries fluoride mouthwashes and rinses.

The agency indicated in the tentative final monograph (50 FR 39857) that the safety of dentifrice pastes containing up to 260 mg fluoride can be attributed to: (1) The decreased amount of fluoride actually available for absorption because of the reactivity of fluoride with the abrasive in dentifrice pastes; and (2) the likelihood that the amount of dentifrice that contains a toxic dose of fluoride

could not be ingested without vomiting. The comment provided no information or data on the effect of glycerin in a dental gel with regard to vomiting in support of its contention that larger package sizes be allowed for the gel dosage form. Without data, the agency cannot determine glycerin's role on vomiting if large amounts of a dental gel were to be ingested. In conclusion, the agency does not consider the comment's arguments supportive of its requests that 0.4 percent stannous fluoride gels remain prescription drugs or that the 120-mg package size be increased for such products marketed on an OTC basis.

E. Comments on Combination Anticaries Drug Products

31. One comment submitted new data and information to support the safety and effectiveness of a combination drug product containing 0.05 percent sodium fluoride and 1.5 percent hydrogen peroxide. The comment stated that this combination drug product, which was not considered in the tentative final monograph for OTC anticaries drug products, is targeted for once-daily use in an orthodontic population. The comment contended that this combination of ingredients provides rational, concurrent therapy as an oral cleanser and anticaries agent for orthodontic patients for two reasons: (1) Orthodontic appliances occasionally cause minor irritation or injury to the oral mucosa and the product cleanses these irritations or injuries, and (2) the configuration of the orthodontic appliance and its duration of use may cause decalcification of teeth in orthodontic patients and the product reduces tooth decalcification.

The comment stated that the safety of the 0.05-percent sodium fluoride component of the product was recognized by FDA in the tentative final monograph for OTC anticaries drug products (50 FR 39854 at 39872). The comment submitted data (Ref. 1) from an enamel solubility reduction test and an enamel fluoride uptake test to support the effectiveness of the sodium fluoride in the combination product. The comment also submitted a clinical study of the combination product to support the safety of daily exposure of the oral mucosa to 1.5 percent hydrogen peroxide for an 18-month period (Ref. 1). The comment added that the effectiveness of up to 3 percent hydrogen peroxide as an oral cleanser was established in the tentative final monograph for OTC oral health care drug products published in the Federal Register of January 27, 1988 (53 FR 2436). Based on these data, the comment requested that the agency include this combination product in the final monograph for OTC anticaries drug products.

The agency agrees that 0.05 percent sodium fluoride and 1.5 percent hydrogen peroxide may be a rational combination for concurrent therapy in orthodontic patients. However, as the agency discussed in the tentative final monograph for OTC oral health care drug products, the Advisory Review Panel on OTC Oral Health Care Drug Products (Oral Cavity Panel) was concerned about the chronic use of hydrogen peroxide in products such as antimicrobial mouthwashes (53 FR 2436 at 2446 and 2447). The agency further stated in this discussion that the effects of long-term OTC use of hydrogen peroxide would be considered as part of the antiseptic segment of the oral health care drug products rulemaking.

After that tentative final monograph was published, the agency published a call-for-data for OTC antiplaque drug products in the Federal Register of September 19, 1990 (55 FR 38560). The data submitted to the agency as a result of this call-for-data will be evaluated by the Dental Products Panel. That Panel will consider, among other things, the safety of the long-term oral use of hydrogen peroxide solutions. The agency believes that the Dental Products Panel is the appropriate forum to consider whether a combination product containing 0.05 percent sodium fluoride and 1.5 percent hydrogen peroxide can be generally recognized as safe and effective for long-term OTC use in the oral cavity. The agency has informed the manufacturer that it considers the combination product to be a new drug that may not be introduced or delivered for introduction into interstate commerce without an approved NDA (Ref. 2). The agency has deferred this product to the Dental Products Panel and will address the submitted data as part of the OTC oral health care rulemaking applicable to antiplaque drug products.

References

(1) Comment No. C80, Docket No. 80N–0042, Dockets Management Branch.

(2) Letter from R. J. Chastonay, FDA, to R. Finn, Chesebrough-Pond's USA Co., in OTC Vol. 08AFM, Docket No. 80N–0042, Dockets Management Branch.

32. Two comments requested the agency to include the combination of sodium fluoride with sodium monofluorophosphate in a dentifrice in the final monograph. The comments contended that the combination of two Category I fluoride ingredients, particularly sodium fluoride and sodium monofluorophosphate, provides a rational combination that has an enhanced therapeutic effect and satisfies the agency's combination policy in § 30.10(a)(4)(iv) (21 CFR 330.10(a)(4)(iv)).

One comment submitted two clinical studies (Refs. 1 and 2) to support the combination of two fluoride ingredients in a dentifrice. The first study (Ref. 1) was a 3-year double-blind, randomized clinical study involving 799 children 14 to 15 years old. Two combination dentifrices, each containing 0.76 percent sodium monofluorophosphate (1,000 ppm theoretical total fluorine) and 0.10 percent sodium fluoride (455 ppm theoretical total fluorine) (to provide a theoretical total fluorine level of 1,455 ppm) were compared with a fluoride-free control dentifrice and with a positive control 0.76 percent sodium monofluorophosphate dentifrice (1,000 ppm theoretical total fluorine). One of the two experimental combination fluoride dentifrices had an alumina abrasive system. The other had a dicalcium phosphate abrasive system. The combination dentifrices reduced the incidence of dental caries by approximately 26 percent compared with the fluoride-free placebo dentifrice, and by approximately 15 percent compared with the positive control 0.76 percent sodium monofluorophosphate dentifrice with an alumina abrasive system.

The second study (Ref. 2) was a 3-year clinical trial that involved school children who resided in an area with nonfluoridated water. Two combination dentifrices containing sodium monofluorophosphate and sodium fluoride, either 1,450 or 2,000 ppm theoretical total fluorine, were compared to a sodium monofluorophosphate dentifrice containing 1,000 ppm theoretical total fluorine. Results indicated that after 3 years of unsupervised brushing, the children who used either the 1,450- or 2,000-ppm fluoride dentifrice combinations developed fewer cavities than those who brushed with the 1,000-ppm sodium monofluorophosphate dentifrice. No significant difference in caries reduction between the 1,450-ppm and 2,000-ppm fluoride dentifrices was reported.

Another comment submitted laboratory and clinical data (Ref. 3) to support the safety and effectiveness of a dentifrice containing sodium fluoride (1,000 ppm) and sodium monofluorophosphate (420 ppm). In one study, enamel specimens exposed for 24 hours to a suspension of sodium monofluorophosphate alone or in combination with sodium fluoride had

greater fluoride uptake with the combination fluorides than with sodium monofluorophosphate alone. In another study, a nearly three-fold reduction in enamel solubility was shown with the combination of sodium fluoride and sodium monofluorophosphate compared to sodium monofluorophosphate alone. The comment also provided a graph of enamel solubility reduction data from dentifrices containing sodium fluoride or sodium monofluorophosphate alone or various combinations of sodium monofluorophosphate and sodium fluoride. The comment noted that a combination containing 75 percent sodium fluoride and 25 percent sodium monofluorophosphate would be optimal. The comment contended that this combination produces twice as much reduction in enamel solubility as either of the ingredients alone at comparable fluoride concentrations.

The comment included an animal study in which male rat pups were inoculated with streptococci (strain not provided) and placed on a standard cariogenic diet for 3 weeks. During this period, the teeth were brushed with a sodium monofluorophosphate/sodium fluoride dentifrice combination or a control fluoride dentifrice (active ingredient and strength not specified). The results of this study indicated that the combination of sodium fluoride and sodium monofluorophosphate was significantly more ''cariostatic'' than the single fluoride dentifrice.

The comment also mentioned a 3-year clinical study involving 573 school children. This study was designed to determine the anticaries effect of a dentifrice containing a sodium monofluorophosphate/sodium fluoride combination (1,420 ppm) with a comparable control toothpaste containing only sodium monofluorophosphate (1,315 ppm). After 2 and 3 years of unsupervised brushing, the number of new decayed, missing, or filled (DMF) surfaces was 12 to 50 percent lower in the combination fluoride group than in the sodium monofluorophosphate control group. Based on the results of this study, the comment concluded that the combination of sodium fluoride and sodium monofluorophosphate is significantly more effective than sodium monofluorophosphate alone in reducing the incidence of dental cavities.

The comment acknowledged that combinations of fluoride active ingredients have not been marketed in the United States. The comment stated, however, that the combination of sodium fluoride and sodium monofluorophosphate has been widely available in the United States for many years. The comment stated that this combination occurs as a result of the hydrolysis of sodium monofluorophosphate during contact with the tooth surface and during the aging process of the fluoride dentifrice formulation itself. The comment indicated that as the dentifrice ages, sodium monofluorophosphate undergoes hydrolysis resulting in a significant increase of sodium fluoride within the sodium monofluorophosphate formulation. The comment added that in the oral environment sodium fluoride may represent more than 50 percent of the hydrolyzed fluoride species in contact with the tooth surface as a result of the hydrolysis of sodium monofluorophosphate alone. The comment included several studies showing that sodium monofluorophosphate undergoes rapid hydrolysis in saliva and even more rapid hydrolysis in the presence of plaque microorganisms. In one study (Ref. 3), during a short period of toothbrushing, the levels of fluoride ions in saliva were initially much lower with the sodium monofluorophosphate dentifrice than with the comparable sodium fluoride preparation. However, after 10 minutes in saliva, both dentifrice formulations provided almost similar levels of fluoride ions. The comment stated that the uncontrolled hydrolysis of the two fluoride agents results in an important, but suboptimal, increase in the bioavailability of fluoride ions. The comment indicated that a combination of fluoride ingredients may provide greater product stability if the agency allows manufacturers the opportunity to control the ratio of these two fluoride ingredients in the dentifrice formulation. According to the comment, this would be better than relying on the unpredictable chemical process of hydrolysis to create a fluoride combination product. The comment asserted that its dentifrice product controls the process of hydrolysis by providing a combination fluoride dentifrice with a fluoride ingredient ratio of 3 to 1 (sodium fluoride to sodium monofluorophosphate), thereby enhancing the therapeutic effect of the anticaries product. However, the comment did not indicate how it proposed to control the hydrolysis of the one-quarter proportion of sodium monofluorophosphate in its product. This information is particularly significant if the hydrolysis of sodium monofluorophosphate occurs as rapidly in the mouth as the comment indicated.

The comment maintained that the fluoride ion is the effective anticaries moiety, and it is irrelevant whether the fluoride ion comes from one fluoride salt or a combination of two fluoride salts, as long as the fluoride ion is present in safe and effective quantities. The comment concluded that these data demonstrate the safety and effectiveness of the combination of sodium fluoride and sodium monofluorophosphate in a dentifrice product. The comment urged the agency to include the combination of sodium fluoride with sodium monofluorophosphate in a 3 to 1 ratio as a dentifrice in the final monograph.

The agency has reviewed the available data and concludes that they do not support the comments' claims. The data do not demonstrate the cariostatic superiority of combination dentifrices containing sodium fluoride and sodium monofluorophosphate compared to conventionally formulated 0.76 percent sodium monofluorophosphate dentifrices. The data do not show that the effect of the sodium fluoride/sodium monofluorophosphate combination is greater than the effect achieved by the individual active ingredients alone at comparable fluoride ion concentrations.

A combination drug product containing Category I active ingredients from the same therapeutic category must satisfy the criteria in § 330.10(a)(4)(iv). The ''General Guidelines for OTC Drug Combination Products, September 1978'' give clarifying examples regarding the combination policy (Ref. 4). Paragraph 3 of these guidelines states:

> 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 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.

The agency has not received sufficient data to conclude that the use of a combination fluoride product has an advantage over or is more effective in controlling the incidence of dental caries than a product containing a single fluoride active ingredient at comparable fluoride ion concentrations.

In the clinical studies submitted by the comment, there was no comparison of a combination and single ingredient product at comparable fluoride concentrations. The agency notes that

the higher levels of fluoride concentration in the combination dentifrices, 1,455 ppm (Ref. 1) and 1,450 or 2,000 ppm (Ref. 2), as compared to the fluoride levels in the positive control single fluoride ingredient dentifrice (1,000 ppm), most likely account for the enhanced effectiveness of the combination products. Because of these higher concentrations, the presence of two sources of fluoride ions may be unrelated to the observed increase in effectiveness.

The agency has also evaluated two other clinical studies (Refs. 6 and 7) that compared comparable fluoride concentrations (1,000 ppm) for a single-ingredient sodium monofluorophosphate dentifrice and a combination containing sodium fluoride and sodium monofluorophosphate. In these studies, the two dentifrices were comparably effective. One study (Ref. 6) was a 31-month, double-blind clinical study involving 1,027 school-aged children. The anticaries effectiveness of a single fluoride ingredient dentifrice containing sodium monofluorophosphate (1,000 ppm theoretical total fluorine) was compared with a combination fluoride dentifrice containing sodium fluoride and sodium monofluorophosphate (1,000 ppm theoretical total fluorine, with 500 ppm contributed by each fluoride ingredient). During this study, the children brushed daily in school under supervision and were clinically and radiologically examined annually. After 31 months of use, no statistically significant difference in the incidence of dental caries was observed between children in the two dentifrice groups.

In the second study (Ref. 7), the effectiveness of three dentifrices was compared over a 2-year period. The study involved 2,769 children; a nearly equal number did unsupervised brushing at home with one of the following dentifrices: (1) Sodium monofluorophosphate (1,000 ppm), (2) a combination of sodium fluoride and sodium monofluorophosphate containing equimolar amounts of each active ingredient (theoretical total fluorine of 1,000 ppm), or (3) a combination of sodium fluoride and sodium monofluorophosphate containing equimolar amounts of each active ingredient (theoretical total fluorine of 2,500 ppm). The results of this study indicated no significant differences in caries inhibition among the dentifrices tested.

In most of the in vitro studies submitted (Ref. 3), exposure times of the tooth enamel surface to suspensions of dentifrice were for lengthy periods of time ranging from 30 minutes to 24 hours. The agency questions the relevancy of a 24-hour exposure time when the exposure time to a dentifrice formulation in the mouth during actual toothbrushing is a few minutes only. In the animal study measuring the effect of three dentifrices on the incidence of caries in rats, no details were given regarding the active ingredients or the fluoride concentrations in the dentifrices tested. Regarding hydrolysis during the aging process of sodium monofluorophosphate products, the Panel stated that sodium monofluorophosphate exists in water in dynamic equilibrium with sodium fluoride, and with the various ions produced by the hydrolysis of the compound (45 FR 20666 at 20674). The agency does not consider this reaction as producing a combination drug product. The agency considers the sodium monofluorophosphate compound as a single active ingredient, even though it is aware that the compound always contains some amounts of sodium fluoride.

In conclusion, the agency has determined that the submitted information and data do not demonstrate the cariostatic superiority of combination dentifrices containing sodium fluoride and sodium monofluorophosphate relative to single-ingredient fluoride dentifrices with a comparable fluoride ion concentration. Accordingly, these fluoride combinations are not included in this final monograph.

References

(1) Hodge, H. C. et al., ''Caries Prevention by Dentifrices Containing a Combination of Sodium Monofluorophosphate and Sodium Fluoride,'' *British Dental Journal*, 149:201–204, 1980.

(2) Diodati, R. R. et al., ''Clinical Anticaries Effect of Various Fluoride Dentifrices,'' Abstract No. 258, *Journal of Dental Research*, 65:198, 1986.

(3) Comment No. C00059, Docket No.80N–0042, Dockets Management Branch.

(4) Food and Drug Administration ''General Guidelines for OTC Drug Combination Products, September 1978,'' Docket No. 78D–0322, Dockets Management Branch.

(5) Conti, A. J. et al., ''A 3-Year Clinical Trial to Compare Efficacy of Dentifrices Containing 1.14 Percent and 0.76 Percent Sodium Monofluorophosphate,'' *Community Dental Oral Epidemiology*, 16:135–138, 1988.

(6) Juliano, G. F. et al., ''Clinical Study Comparing the Anticaries Effect of Two Fluoride Dentifrices,'' Abstract No. 131, *Journal of Dental Research*, 64:189, 1985.

(7) Ripa, L. W. et al., ''Clinical Comparison of the Caries Inhibition of Two Mixed NaF-Na_2PO_3F Dentifrices Containing 1,000 and 2,500 ppm F Compared to a Conventional Na_2PO_3F Dentifrice Containing 1,000 ppm F: Results after Two Years,'' *Caries Research*, 21:149–157, 1987.

F. Comments on Testing Guidelines

33. One comment agreed with the agency's conclusion that laboratory test data are not adequate to establish comparative claims of effectiveness for anticaries active ingredients (53 FR 22430 at 22446). However, the comment contended that the agency should recognize the possibility that, in certain cases, claims of superior performance in a laboratory test may be desirable. As a hypothetical example, the comment stated that it may be important to a dental professional that (1) one active ingredient provides more rapid fluoride uptake than another and (2) this performance could promote hardening of enamel in certain instances. The comment suggested that such claims could be made in professional labeling without needing clinical studies for support.

The agency reiterates its conclusion that the extension of laboratory test data to a comparative evaluation of effectiveness between different fluoride products or fluoride active ingredients is inappropriate (53 FR 22446). In general, the agency does not believe that claims of superior performance in a laboratory test are appropriate for use in either the consumer or professional labeling of OTC anticaries drug products unless that superior performance has been shown to have clinical significance. However, the agency will evaluate any such laboratory test data submitted on a case-by-case basis.

34. One comment (from an agency dental reviewing officer) objected to the use of Laboratory Testing Profiles (LTP's) for final formulation testing for Category I active ingredients in fluoride dentifrice formulations. The comment expressed unawareness of any data submitted to the agency demonstrating that the results from the biological test requirements in the LTP's were correlated with adequate and well-controlled anticaries clinical studies. The comment did not submit any data demonstrating that the LTP's do not correlate with clinical studies.

Two comments (from manufacturers) concurred with the agency's proposal that the LTP's be used to ensure the effectiveness of abrasive-containing fluoride drug products. One of the comments contended that, based on the current state of dental research, it is not necessary to do clinical studies to verify anticaries performance except in certain situations, such as the introduction of a new anticaries active ingredient.

Regarding the comment questioning whether the LTP's were correlated with

adequate and well-controlled clinical testing, the agency notes that the Panel based its recommendations on the results of actual biological tests performed on fluoride dentifrices that had been shown to be clinically effective in preventing caries (45 FR 20666 at 20677). Thus, the Panel's recommendations were based on the correlation of laboratory testing results with clinical results.

The agency considers the LTP final formulation test requirements in this final monograph to be adequate to ensure the safety and effectiveness of dentifrices containing fluoride active ingredients included in the monograph. In the tentative final monograph (53 FR 22430 at 22433), the agency stated reasons why it concurred with the Panel's recommended laboratory testing requirements, as set forth in the Panel's LTP tables (45 FR 20666 at 20679 to 20681) for Category I fluoride ingredient/abrasive combinations. Thus, the agency concludes that lengthy clinical trials are not necessary to ensure the safety and effectiveness of dentifrices containing monograph fluoride ingredients.

35. One company asked whether the monograph would preclude FDA's accepting valid clinical trials in lieu of LTP's. The comment noted the agency's statement in the tentative final monograph that the use of LTP's to establish efficacy should not in any way preclude the option of clinical testing as a final demonstration of efficacy for those companies that prefer to use this method (53 FR 22430 at 22434).

The monograph does not preclude manufacturers from performing clinical testing to ensure the effectiveness of a fluoride dentifrice. However, the regulatory requirement for all fluoride dentifrice drug products marketed pursuant to the monograph is that the product must meet the final formulation test requirements (LTP's) included in § 355.70.

36. One comment stated that all toothpaste advertised as containing fluoride should be tested for stannous fluoride concentration, per unit volume or weight. The comment contended that this is necessary to ensure that the concentration of stannous fluoride is not being reduced.

There are a number of requirements applicable to fluoride dentifrices that will ensure the fluoride concentration of the product. While toothpastes can contain one of several different fluoride ingredients, the LTP's included in the final monograph are intended to ensure available fluoride ion in the final products. The aged minimal fluoride ion values in the LTP tables are used to determine the product's expiration date. This date provides consumers relevant information regarding use of the product. In addition, § 211.166 of the agency's current good manufacturing practice regulations (21 CFR 211.166) contains stability testing requirements for drug products, including toothpastes. Accordingly, these requirements address the comment's concern.

37. Two comments requested that the agency revise LTP Table 3 to include corrected test values submitted by the industry for stannous fluoride dentifrices (45 FR 20666 at 20681). One comment noted that the agency's revisions in the LTP tables discussed in the tentative final monograph (53 FR 22430 at 22435 and 22436) omitted a correction mentioned in an earlier comment concerning stannous fluoride that was made to this rulemaking. The comment requested that the agency revise Table 3 under ''II. Soluble Stannous Ion,'' by inserting a statement indicating that the test dilution for the silica abrasive should remain 1:10 as stated in the tentative final monograph (45 FR 20666 at 20681). The second comment indicated that the appropriate values for soluble fluoride should discriminate between dentifrices using insoluble sodium metaphosphate and silica abrasives. The comment indicated that in Table 3 for stannous fluoride dentifrices (45 FR 20681) under ''I. Soluble Fluoride Ion,'' the test values for fluoride ion listed for the silica abrasive formulation should be 600 ppm for the fresh value and 500 ppm for the aged minimal value with a test dilution of 1:10, rather than 700 ppm for the fresh value and 650 ppm for the aged minimal value. The comment stated that this revision would discriminate between dentifrices using insoluble sodium metaphosphate and those using silica abrasives.

The agency recognizes that the data the Panel used to establish the LTP tables were developed by industry and submitted to the Panel to provide a basis for the LTP tables. The agency has reviewed the industry's corrections of the LTP tables as noted above and agrees that these corrections should be made. However, the agency does not find it necessary to insert an additional clarification statement in the corrected LTP tables as requested by one comment. Instead, the agency has revised the LTP tables to reflect the changes made to the tables in the tentative final monograph (53 FR 22435 and 22436) and in this final monograph (see section I.B., comments 10, 13, 14, and 15 of this document, and section I.F., comments 38, 39, and 42 of this document) as follows:

TABLE 1.—ACCEPTABLE TEST VALUES FOR 1,000 PPM THEORETICAL TOTAL FLUORINE SODIUM FLUORIDE DENTIFRICES IN A PASTE DOSAGE FORM

I. Soluble Fluoride Ion (F^-)

Abrasive	Fresh F^- value[1]	Aged minimal F^- value [1,2]	Test dilution (w/w)
High-beta-phase calcium pyrophosphate	648 ppm	403 ppm	1:3

II. Hydrogen Ion Concentration (pH)

Abrasive	Test value	Test dilution (w/w)
High-beta-phase calcium pyrophosphate	6.5 to 8.0	1:3

[1] Values listed are parts of the measured substance per million parts of the whole dentifrice.

[2] Values listed are intended for use in determining expiration dating for fluoride dentifrices covered by the final monograph. These values are not intended to be used to determine if a dentifrice meets monograph requirements, i.e., is safe and effective.

TABLE 2.—ACCEPTABLE TEST VALUES FOR 1,000 PPM THEORETICAL TOTAL FLUORINE SODIUM MONOFLUOROPHOSPHATE DENTIFRICES IN A PASTE DOSAGE FORM

I.Soluble Fluoride Ions ($PO_3F^=$ and F^-)[1]

Abrasive	Ion	Fresh value[2]	Aged minimal value[2,3]	Test dilution (w/w)
Applicable to all abrasives	$PO_3F^=$	650 ppm[4]	Half total ($PO_3F^=$ and F^-) value	1:10
	F^-	10 to 150 ppm	10 ppm to $PO_3F^=$ value	1:10
	Total ($PO_3F^=$ and F^-)	800 ppm	600 ppm	1:10

II.Hydrogen Ion Concentration (pH)

Abrasive	Test value	Test dilution (w/w)
Alumina	6.4 to 9.0	1:10
Calcium carbonate	7.0 to 10.0	1:10
Calcium pyrophosphate	5.0 to 5.4	1:10
Dicalcium phosphate	6.3 to 7.6	1:10
Insoluble sodium metaphosphate	5.6 to 6.9	1:10
Silica	5.5 to 7.4	1:10

[1] For the compound sodium monofluorophosphate in a dentifrice formulation, fluoride ion exists as a combination of the ions $PO_3F^=$ and F^-. Values are given for each of these ions as well as the ''Total'': combination of $PO_3F^=$ plus F^-.
[2] Values listed are parts of the measured substance per million parts of the whole dentifrice.
[3] Values listed are intended for use in determining expiration dating for fluoride dentifrices covered by the final monograph. These values are not intended to be used to determine if a dentifrice meets monograph requirements, i.e., is safe and effective.
[4] Soluble PO_3 is derived either by direct analytical measurement or by subtracting soluble fluoride ion (F^-) from total soluble available fluoride ($PO_3F^=$ plus F^-).

TABLE 3.—ACCEPTABLE TEST VALUES FOR 1,000 PPM THEORETICAL TOTAL FLUORINE STANNOUS FLUORIDE DENTIFRICES IN A PASTE DOSAGE FORM

I. Soluble Fluoride Ion (F^-)

Abrasive	Fresh F^- value[1]	Aged minimal F^- value[1,2]	Test dilution (w/w)
Insoluble sodium metaphosphate	700 ppm	650 ppm	1:3
Silica	600 ppm	500 ppm	1:10
Calcium pyrophosphate	288 ppm	108 ppm[3]	1:3

II. Soluble Stannous Ion (Sn^{++})

Abrasive	Fresh Sn^{++} value[1]	Aged minimal Sn^{++} value[1,2]	Test dilution (w/w)
Insoluble sodium metaphosphate	2,000 ppm	Qualitatively detectable	1:10
Silica	Qualitatively detectable	Qualitatively detectable	1:10
Calcium pyrophosphate	900 ppm	Qualitatively detectable	1:3

III. Hydrogen Ion Concentration (pH)

Abrasive	Test value	Test dilution (w/w)
Insoluble sodium metaphosphate	4.2 to 5.4	1:4
Silica	4.6 to 5.1	1:4
Calcium pyrophosphate	4.4 to 5.1	1:3

[1] Values listed are parts of the measured substance per million parts of the whole dentifrice.
[2] Values listed are intended for use in determining expiration dating for fluoride dentifrices covered by the final monograph. These values are not intended to be used to determine if a dentifrice meets monograph requirements, i.e., is safe and effective.
[3] Value corresponds to that of aged product found clinically effective.

TABLE 4.—ACCEPTABLE TEST VALUES FOR ALL OTC FLUORIDE DENTIFRICES IN A PASTE DOSAGE FORM

I. Theoretical Total Fluorine[1]

TABLE 4.—ACCEPTABLE TEST VALUES FOR ALL OTC FLUORIDE DENTIFRICES IN A PASTE DOSAGE FORM—Continued

A. 850 to 1,150 ppm for all active ingredients
B. 1,500 ppm for sodium monofluorophosphate

II. Available Fluoride Ion Concentration[1]	
Active Ingredient	*Minimum Available Fluoride Ion*[1]
A. *For 850 to 1,150 ppm Dentifrices*:	
Sodium fluoride	≥ 650 ppm
Sodium monofluorophosphate	≥ 800 ppm (consisting of $PO_3F^=$ and F^- combined)
Stannous fluoride/calcium pyrophosphate	≥ 290 ppm
Stannous fluoride/with abrasive other than calcium pyrophosphate	≥ 700 ppm
B. *For 1,500 ppm Dentifrices*:	
Sodium Monofluorophosphate	≥ 1,275 ppm (consisting of $PO_3F^=$ and F^- combined)

III. Total Fluorine in Milligram Per Milliliter Dentifrice
A. *For 850 to 1,150 ppm Dentifrices*:
0.935 to 1.955
B. *For 1,500 ppm Sodium Monofluorophosphate Dentifrices*:
1.650 to 2.550

[1] Values listed are parts of the measured substance per million parts of the whole dentifrice.

TABLE 5.—ACCEPTABLE TEST VALUES FOR SODIUM FLUORIDE/SODIUM BICARBONATE POWDERED DENTIFRICES CONTAINING 1,000 PPM THEORETICAL TOTAL FLUORINE

I. Theoretical Total Fluorine[1]
850 to 1,150 ppm
II. Minimum Available Fluoride Ion[1]
850 ppm
III. Poured-bulk Density Range in Gram Per Milliliter Dentifrice
1.0 to 1.2
[1] Values listed are parts of the measured substance per million parts of the whole dentifrice.

TABLE 6—BIOLOGICAL TESTING REQUIREMENTS FOR ALL DENTIFRICES IN PASTE AND POWDER DOSAGE FORMS

I. Animal Caries Reduction
and,
II. One of the Following Tests:
A. Enamel Solubility Reduction
B. Fluoride Enamel Uptake

38. One comment concurred with the agency's statement (53 FR 22430 at 22435) that measurements such as specific gravity, pH, stannous ion content, maximum test dilution, and lower limit of available fluoride at the expiration date should not be included in the final monograph. The comment agreed that these measurements are adequately addressed in the current good manufacturing practices (CGMP) regulations. The comment stated that the CGMP regulations in part 211 (21 CFR part 211) provide for acceptable outcomes of the performing, validating, recording, and reporting of procedures in drug manufacturing, but the CGMP regulations do not provide test methods or acceptable values of measurement.

The comment provided the following example: If control of pH is important in manufacturing a dentifrice, the CGMP regulations provide that it is necessary to institute and document procedures for ensuring accurate recording, control of pH during the process, and acceptable checking of equipment. However, the comment stated that the regulations do not specify equipment, measurements, or the proper pH range. The comment contended that one could reasonably conclude that omission of pH, specific gravity, stannous ion concentration, or maximum test dilutions from the provisions of the monograph means that manufacturers may set these specifications as they see fit.

However, the comment added that there are other statements in the agency's discussion of LTP's that cast doubt on the above interpretation. As an example, the comment cited the phrase ''the allowable range for specific gravity (1.1 to 1.7) and theoretical total fluoride (850 to 1,150 ppm) * * *'' (53 FR 22430 at 22437). The comment noted that, even though these ranges are given

equal force in this discussion, theoretical total fluoride is specified in proposed § 355, while specific gravity is not. The comment also mentioned the Panel's recommendations regarding specific pH guidelines (53 FR 22443) and the agency's statement that ''* * * manufacturers should use the aged minimal fluoride ion limits provided in the LTP Tables * * * to determine the expiration dates for fluoride dentifrices * * *'' (53 FR 22445). The comment added that the third agency change in the Panel's recommendations states that the agency is proposing the LTP values of pH and specific gravity (but not stannous ion levels, maximum test dilutions, or aged minimal fluoride levels) as guidelines of appropriate testing limits. The comment requested that the agency clarify its position on these matters.

The agency's proposal (53 FR 22430 at 22434 and 22435) states that fluoride dentifrices shall: (1) Meet or exceed the soluble fluoride ion level specified for each particular fluoride ingredient listed in the monograph, and (2) meet the requirements for biological testing. The agency included these criteria in the proposed monograph. Furthermore, the agency is including requirements pertaining to available fluoride content and biological testing in this final monograph. (See section I.F., comment 40 of this document.) These requirements must be satisfied for an anticaries dentifrice to be considered generally recognized as safe and effective.

The agency stated in the tentative final monograph (53 FR 22430 at 22435) that certain recommended requirements in the LTP tables are adequately addressed in the CGMP regulations (21 CFR part 211) and need not be specifically addressed in the monograph. These included parameters such as specific gravity and pH, which relate to inactive ingredients and appropriate manufacturing procedures. The CGMP regulations require establishing and following test methods and specifications that are appropriate and scientifically sound. These required methods and specifications may be found in a variety of sources (e.g., the United States Pharmacopeia/National Formulary or codified monographs).

The discussion about testing parameters not specifically included in the monograph (such as pH, specific gravity (w/v), stannous ion concentration, aged minimal fluoride ion values, and test dilution) was intended as guidance only. While these parameters are important to the manufacturer's product, only those requirements specifically set out in the final monograph are considered essential by the agency and must be met. In the preamble to the tentative final monograph (53 FR 22435 and 22436), the agency revised the Panel's recommended testing guidelines for a number of testing parameters. The agency intended that these testing values be used solely as guidance for fulfilling CGMP requirements.

In this document, the agency has further revised the proposed testing guidelines for parameters other than available fluoride ion and biological test requirements (see section I.F., comments 35 and 39 of this document). These revised parameters are also intended only as guidance, e.g., for use in determining expiration dating. The agency is including a revised LTP chart in the preamble of this document for informational purposes (see section I.F., comment 37 of this document).

39. One comment stated its approval of the agency's proposed modification of the Panel's recommended ranges for theoretical total fluorine. The proposal set out a range of 0.935 to 1.955 mg theoretical total fluorine per mL for dentifrices with a specific gravity lower than 1.1 or higher than 1.7 (53 FR 22430 at 22438). The comment indicated that the proposed modification reflects the dynamic nature of dental research and provides innovation without compromising the required amount of fluoride ion available to the teeth with each brushing. The comment added that this single required range of theoretical total fluorine values more accurately defines the amount of fluoride ions available to the teeth during each brushing. For that reason, the proposed range is more descriptive of products that have been proven clinically effective. The comment suggested that a single theoretical total fluorine range would be better than the two previous proposed ranges of specific gravity and theoretical total fluorine. The comment contended that a single range would ensure consumers that the active ingredient in dentifrice products delivers the required concentration of fluoride ion, thus providing the desired anticaries effect.

In the tentative final monograph for OTC anticaries drug products (53 FR 22430 at 22437), the agency proposed a range of 850 to 1,150 ppm for theoretical total fluorine and a specific gravity range of 1.1 to 1.7. This range of values was intended to accommodate the newer, less dense abrasive systems without compromising the effectiveness of fluoride dentifrices. The agency indicated that these ranges are intended for formulation purposes and not as a variation for quality control purposes. The agency also acknowledges that changes in specific gravity result in a corresponding change in the amount of fluoride contained in a given volume of dentifrice if the concentration of the fluoride is expressed as a weight-to-weight measurement, such as ppm.

The agency also indicated that a fluoride range of 0.935 to 1.955 mg per mL of dentifrice might be appropriate. These weight-to-volume measurements correspond directly to allowable ranges for specific gravity (1.1 to 1.7) and theoretical total fluorine (850 to 1,150 ppm). The agency presented the following guidelines for dentifrices: The lower limits of 850 ppm theoretical total fluorine and a specific gravity of 1.1 convert to a lower limit of 0.935 mg fluorine per mL toothpaste. The upper limits of 1,150 ppm theoretical total fluorine and a specific gravity of 1.7 convert to an upper limit of 1.955 mg fluorine per mL toothpaste. This provides a range of 0.935 to 1.955 mg fluorine per mL toothpaste. This range ensures that fluoride dentifrices with different specific gravities, due to changes in the abrasive system, will contain the same range of total fluoride per volume of dentifrice as specified in the LTP tables. This fluoride range also will provide flexibility to accommodate the development of new abrasive systems.

The agency indicated in an earlier comment (see section I.B., comment 10 of this document) that it is including extra-strength sodium monofluorophosphate dentifrices (1,500 ppm) in this final monograph as generally recognized as safe and effective dentifrice products. Therefore, the agency is also providing a range of 1.65 to 2.55 mg per mL of dentifrice for higher strength dentifrices (1,500 ppm). This range corresponds directly to the allowable ranges for specific gravity (1.1 to 1.7).

The agency concludes that fluoride ranges of 0.935 to 1.955 mg (for all 850 to 1,150 ppm dentifrices) and 1.6 to 2.55 mg (for 1,500 ppm sodium monofluorophosphate dentifrices) theoretical total fluorine per mL toothpaste are appropriate for these Category I fluoride dentifrice formulations, irrespective of their specific gravity. The agency is including these ranges in the revised LTP tables. (See also section I.F., comment 37 of this document.)

40. Several comments addressed the use of LTP's, rather than clinical trials, to predict the anticaries effectiveness of monograph fluoride dentifrices formulated with ''new'' abrasive systems or with anticalculus agents. One comment (from a professional

dental association) objected to the agency's proposal in the tentative final monograph (53 FR 22430 at 22442) to allow LTP's for this testing. The comment contended that all fluoride-containing dentifrice products should either be clinically tested or should be equivalent to clinically tested products. The comment stated that the agency's proposed LTP's would permit marketing of any dentifrice product containing an established fluoride agent regardless of whether or not the abrasive system had been clinically tested. The comment argued that, because of the very limited nature of the monograph LTP's, there is no assurance of the availability of fluoride ions during the time of brushing. The comment added that abrasives can play a very critical role in the rate of release/availability of the active ingredient. Furthermore, the comment stated that the LTP's proposed in the tentative final monograph assess the steady state level of release of the active species. This value, according to the comment, has no meaning in examining the potential efficacy of fluoride dentifrice products. The comment maintained that only clinically tested fluoride/abrasive systems should be eligible for review under the OTC drug monograph system. The comment added that any fluoride dentifrice with an untested abrasive system should be required to supply clinical data demonstrating effectiveness. The comment stated that its association had established testing guidelines designed to demonstrate equivalency of fluoride agents provided that the formulations have a fluoride/abrasive system similar to a clinically effective product.

The comment also contended that fluoride dentifrices containing agents that inhibit calculus formation, thus influencing the calcification/decalcification process associated with caries, should be required to submit a more extensive LTP than the agency had proposed in the tentative final monograph (53 FR 22430 to 22448). The comment recommended that either animal caries or remineralization studies be required for these products. The comment stated that such studies would evaluate the potential inactivation of the fluoride agent by a secondary nontherapeutic additive.

A comment from a manufacturers' association objected to the first comment's position, contending that no data or other information were submitted to rebut the agency's LTP proposal. The comment also disagreed with the dental association's contention that calculus inhibiting agents can influence the calcification/decalcification process associated with caries. The comment submitted three clinical studies (Refs. 1, 2, and 3) to demonstrate that the inclusion of anticalculus agents in fluoride-containing dentifrices does not interfere with the anticaries effectiveness of these products. The comment noted that three clinically proven anticalculus agents (pyrophosphate salts, zinc chloride, and zinc citrate) are currently marketed in dentifrices in the United States. According to the comment, these agents have been shown not to adversely affect fluoride activity in three biological tests that were included in the tentative final monograph (53 FR 22430 at 22447). The comment objected to the dental association's position concerning the validity of using LTP's to predict the anticaries effectiveness of fluoride dentifrices with an anticalculus agent, contending that the dental association's concern is not warranted by existing scientific data. The comment indicated that it would be a waste of scarce resources and funds to require further clinical testing when laboratory tests can accurately determine whether or not anticalculus agents interfere with fluoride efficacy. The comment requested that the agency continue to require only LTP's as set forth in the tentative final monograph (53 FR 22430 at 22434).

The agency recognizes that inactive ingredients, such as abrasives and anticalculus agents, can play an important role in the rate of release/availability of fluoride from a fluoride compound during the time period of toothbrushing. Although the analytical tests do not directly measure the availability of fluoride ions during the time of toothbrushing, the biological tests indicate that the fluoride ion is active in preventing dental caries. In addition, one of the biological tests, the animal caries reduction, directly measures the anticaries effectiveness of a fluoride dentifrice product in an animal model in vivo after a limited brushing time. The severity of caries in each group is computed, and a favorable result for the test sample indicates that the fluoride ion has activity. The test sample is compared with a U.S.P. fluoride dentifrice reference standard that has been proven effective in clinical studies.

In the tentative final monograph (53 FR 22430 at 22433 and 22440, comments 4 and 11), the agency discussed why lengthy clinical trials are no longer warranted. The comments did not provide any new data or information to alter that conclusion. The agency determined that appropriate laboratory testing, including biological testing, is adequate to ensure the effectiveness of dentifrices containing monograph fluoride ingredients. The agency indicated that the Panel based its development of LTP's on laboratory testing results from studies on fluoride dentifrice formulations that had actually been clinically tested and found effective. The agency agreed with the Panel's view that a monograph fluoride ingredient/abrasive system in a dentifrice formulation not specifically reviewed by the Panel, must contain an amount of available fluoride ion equal to or greater than the highest available fluoride ion value recommended for the specific fluoride ingredient. This requirement applies to fluoride dentifrices that contain a monograph fluoride ingredient and either (1) a new abrasive ingredient (not previously included in marketed dentifrices) or (2) an abrasive ingredient included in previously marketed dentifrices in a combination not specifically reviewed by the Panel (53 FR 22430 at 22441). The agency proposed that fluoride dentifrices must meet or exceed the soluble fluoride ion level specified for each particular fluoride ingredient listed in the monograph and meet the test requirements of any two of the following biological tests: (1) Enamel solubility reduction (ESR), (2) fluoride uptake by enamel, and/or (3) animal caries reduction (53 FR 22430 at 22434).

The agency does not agree that one of the clinical studies (Ref. 1) submitted by one comment adequately demonstrates whether or not an anticalculus additive affects the anticaries effectiveness of a dentifrice. The study did not include a positive control (Category I) fluoride toothpaste in the experimental design. Instead, a fluoride/anticalculus dentifrice was compared to a negative control toothpaste (not containing either fluoride or anticalculus agent). However, the two other studies (Refs. 2 and 3) submitted by the comment clearly indicate that the anticaries effectiveness of the dentifrice formulations tested was not adversely affected by the anticalculus agents used in the studies. In one study (Ref. 2), three dentifrices containing 1,000, 1,500, or 2,500 ppm fluoride (as sodium monofluorophosphate) and an anticalculus agent (0.5 percent zinc citrate trihydrate) were compared with dentifrices that contained the same fluoride concentrations but no anticalculus agent. At the conclusion of the 3-year study, no clinically significant difference was observed between the fluoride dentifrices with or without the anticalculus agent. However, a dose-response effect was

observed at varying fluoride concentrations. In the other clinical study (Ref. 3), three dentifrices containing 1,000 or 1,100 ppm of fluoride (as sodium fluoride and sodium monofluorophosphate) and different anticalculus ingredients (3.3 percent soluble pyrophosphate, 2 percent zinc chloride, and 1.25 percent unspecified zinc compound) were evaluated. The three dentifrices produced anticaries protection similar to a control sodium monofluorophosphate toothpaste containing 1,000 ppm fluoride, but without an anticalculus ingredient. These two clinical studies corroborate that these anticalculus agents do not interfere with the anticaries effectiveness of the fluoride active ingredients sodium fluoride and sodium monofluorophosphate.

The agency is concerned that newer abrasives and anticalculus agents may reduce the availability of fluoride ions, and that this reduction may not be detected by the chemical tests suggested in the LTP's. These chemical tests may not always reflect the true anticaries effectiveness of fluoride dentifrices with or without additives in situ when diluted in the mouth by saliva or exposed to the subtle reactions between dentifrice ingredients and salivary components. Although these in vitro tests may show positive results that are predictive of anticaries activity, during actual use in the mouth the product may not provide the same expected level of anticaries effectiveness. The limitations of in vitro tests are particularly significant in evaluating fluoride toothpastes that contain additives that may affect fluoride ion availability under in situ conditions. For that reason, the agency considers them to be only markers of potential effectiveness, not actual proof.

During one study (Ref. 4), several laboratory tests (including ESR, enamel uptake of fluoride, and animal caries reduction tests) were investigated as indicators of the compatibility of an abrasive system and a fluoride source. Dentifrices containing 1,000 ppm of fluoride (as sodium fluoride, stannous fluoride, or sodium monofluorophosphate) were formulated with abrasives known either to interact or not interact with particular fluorides. The in vitro tests measured fluoride uptake for a considerably longer time period than would be experienced during actual intermittent use. The authors claimed that the in vitro tests provide valuable information. They also stated that the results of the ESR test did not correlate well with the animal caries assay results. Furthermore, the authors noted that the sodium monofluorophosphate dentifrices provided high levels of available active fluoride ions but produced only small reductions in enamel solubility. Thus, this study indicated that the animal caries reduction studies gave the most complete assessment of effectiveness of the dentifrices tested compared with the test results from the two in vitro tests (ESR and enamel uptake of fluoride). Therefore, the agency concludes that both animal and human studies provide a more complete assessments of anticaries effectiveness.

The agency has thoroughly reviewed the comments, the clinical studies involving anticalculus agents added to dentifrice products containing monograph fluoride ingredients, and data comparing the results of in vitro biological tests with in vivo animal caries tests. Based on this evaluation, the agency concludes that biological testing is necessary for all clinically untested dentifrice products to ensure fluoride ion availability. Therefore, the agency is revising the biological testing requirements in this final monograph to require that all OTC anticaries dentifrice drug product formulations not specifically reviewed by the Panel be tested in an animal caries reduction test. This type of biological test will be required rather than optional, as proposed in the tentative final monograph (53 FR 22430 at 22434). Based upon a review of all the available data, the agency still concludes that long-term clinical trials are not needed for different or new dentifrice products containing a monograph fluoride ingredient/abrasive system, including untested abrasive systems or new additives. The agency considers fluoride availability as well as ESR and fluoride uptake studies to be good predictors of potential effectiveness of a fluoride toothpaste. However, the in vivo animal caries reduction test provides further assurance that the dentifrice is active against dental caries. The biological portion of the recommended testing provides an important assurance that, in addition to being chemically available as demonstrated by the analytical portion of the testing recommendations, the fluoride is also bioavailable in that it will alter tooth structure in the biological tests to make the tooth resistant to caries.

Accordingly, the agency is revising the first sentence in § 355.70 of the testing procedures for fluoride dentifrice drug products to read: ''A fluoride dentifrice drug product shall meet the biological test requirements for animal caries reduction and one of the following tests: Enamel solubility reduction or fluoride enamel uptake.''

Although the agency encourages the development of additional testing procedures, such as remineralization tests, the agency considers the three biological tests recommended by the Panel as sufficient at this time to demonstrate anticaries effectiveness. Demineralization/remineralization studies in humans may also be predictive of anticaries effectiveness. However, the agency has not received sufficient data to correlate specifically the results of remineralization tests with clinical studies that demonstrate anticaries effectiveness of fluoride dentifrices. The agency would consider such tests as an option to animal caries reduction tests if adequate data were submitted to the agency in the form of a petition to amend the monograph.

References

(1) Lu, K. H. et al., ''The Effect of a Fluoride Dentifrice Containing an Anticalculus Agent on Dental Caries in Children,'' *Journal Of Dentistry For Children*, 52(6):449–451, 1985.

(2) Stephen, K. W. et al., ''A 3-Year Oral Health Dose-Response Study of Sodium Monofluorophosphate Dentifrices with and without Zinc Citrate: Anti-Caries Results,'' *Community Dentistry and Oral Epidemiology*, 16:321–325, 1988.

(3) Triol, C. W. et al., ''A Clinical Study of the Anticaries Efficacy of Three Fluoride Dentifrices Containing Anticalculus Ingredients: One and Two Year Results,'' *The Journal of Clinical Dentistry*, 1(2):48–50, 1988.

(4) Pader, M. et al., ''The Evaluation of Fluoride Dentifrices,'' *Journal of the Society of Cosmetic Chemistry*, 28:681–694, 1977.

41. One comment stated that it is unclear what the reference standards will be for the required analytical and biological testing of fluoride dentifrices. The comment contended that it is difficult to comment on the whole program without knowing what the standards are. The comment suggested that an additional period of time be permitted to allow interested groups to comment on the acceptability of the actual United States Pharmacopeia (U.S.P.) reference standards when they are established.

In the tentative final monograph, the agency stated that it was coordinating establishment of the fluoride dentifrice reference standard formulations with the United States Pharmacopeial Convention (U.S.P.C.) (53 FR 22430 at 22439). Since then, industry has worked with the U.S.P.C. to establish reference standards, through the joint Nonprescription Drug Manufacturers Association and Cosmetic, Toiletry and Fragrance Association task force. Information about the reference standards was made public in U.S.P.'s Pharmacopeial Forum in 1990 (Ref. 1),

and interested parties had an opportunity to comment at that time. Reference standards have been available from U.S.P.C. since 1990.

Based on the public availability and use of these U.S.P. fluoride dentifrice reference standards by the industry since 1990, the agency concludes that it is not necessary to provide an additional comment period.

Reference

(1) The United States Pharmacopeial Convention, Inc., ''Headquarters Column,'' *Pharmacopeial Forum*, 16:3–4, 1990.

42. Two comments requested that the agency refrain from mandating specific biological test procedures in the final monograph for OTC anticaries drug products. Instead, the two comments requested that the biological test procedures proposed in § 355.70 be considered as guidelines only. The comments agreed with the agency that the substitution of a new test, such as remineralization, for one of the three qualifying biological tests should require a petition for FDA approval. However, the comments strongly disagreed with the need for a petition for minor modifications in the biological testing protocols when the results are at least as valid, reliable, and accurate as the current test procedures. One comment added that, without this flexibility, the acceptance by the agency of even minor changes may take an inordinate period of time without helping to protect the dentifrice user from an ineffective product. The comment suggested that if the agency continues to maintain control over changes in test procedures, approval of the changes should be timely and a list of criteria should be provided so that manufacturers can be assured that changes will be accepted by the agency.

The second comment indicated that mandating specific test protocols tends to discourage scientific experimentation and the application of advanced technology in method development. The comment noted that advances in technology alone will result in changes in test protocols and the precision, sensitivity, and accuracy of various measurements. Therefore, the comment requested that the agency designate the biological testing procedures as guidelines only and explicitly indicate that other valid, reproducible methods are acceptable. The comment indicated that requiring a petition to modify and improve a procedure would not only be time consuming, but also would be expensive and thus not in the interest of consumers. The comment concluded that companies should have the opportunity to make minor modification to test methods as long as the changes are scientifically validated and produce accurate and reliable results.

The agency does not agree that the specific biological testing procedures for fluoride dentifrices should be considered as test guidelines only. The agency indicated in the tentative final monograph (53 FR 22430 at 22443) that the availability of the fluoride ion in a dentifrice formulation and meeting the biological testing requirements are the most important testing criteria for predicting the effectiveness of a fluoride dentifrice product. The agency considers demonstration of the bioavailability of the fluoride ion in the biological tests listed in § 355.70 as necessary to ensure the anticaries effectiveness of fluoride dentifrices. The agency points out that the required biological tests are based on the results of actual biological testing procedures performed on fluoride dentifrices that had been shown to be clinically effective in preventing caries. These testing procedures are a regulatory standard that supports general recognition of the safety and effectiveness of fluoride dentifrices.

The agency has had a similar petition procedure for many years for modifications to the in vitro test for OTC antacid drug products (see 21 CFR 331.29). The agency has processed these petitions in a timely manner. Accordingly, the agency is including the biological testing procedures in § 355.70 as required tests for any fluoride dentifrice drug product marketed pursuant to this monograph.

The agency finds no basis to agree with the comment's suggestion that requiring these specific biological testing procedures interferes with the advancement of science and technology. The agency does not intend for the testing procedures to preclude the application of new, advanced technology in testing fluoride dentifrices. The agency agrees with the two comments that as technology continues to evolve, modifications to the existing testing procedures may result in more sensitive, reliable, and accurate measurements. However, there should be a consensus in the scientific community that these new procedures are generally accepted. The agency encourages the development of new testing technology and methods for fluoride dentifrices and has provided in the monograph the opportunity for interested persons to propose modifications or alternative testing procedures through the petition process in 21 CFR 10.30. Any petition should contain sufficient data to support the modification and to demonstrate that the alternative testing procedure provides results that are equivalent to the currently required biological test methods.

43. Two comments objected to fluoride dentifrice reference standards being provided through the U.S.P.C. The comments suggested that exact specifications for these reference standards (including levels of ingredients, source of raw materials, product specifications, and detailed production directions) be provided as part of the U.S.P. monograph system so that manufacturers could prepare their own fresh reference standards when needed. One comment contended that, given sufficient detailed specifications, manufacturers would certainly be as qualified to produce properly prepared standards as the U.S.P.C.

Following publication of the tentative final monograph, FDA and industry developed procedures for introduction of new or modified commercial dentifrice formulations without full clinical testing, provided that bioavailability/bioequivalence of the formulation was demonstrated against an appropriate reference standard (Ref. 1). Six U.S.P. fluoride dentifrice reference standards were initially established for use in the biological testing of fluoride dentifrices: (1) Sodium fluoride-calcium pyrophosphate (high beta-phase), (2) sodium fluoride-silica, (3) sodium monofluorophosphate-calcium carbonate, (4) sodium monofluorophosphate-dicalcium phosphate, (5) sodium monofluorophosphate-silica, (6) stannous fluoride-silica (Ref. 2). These reference standards are prepared by manufacturers of dentifrice drug products and provided to the U.S.P.C. for distribution. Thus, the agency agrees with one comment that manufacturers are qualified to produce these reference standards. Based on the development of these reference standards by manufacturers of OTC dentifrice drug products, neither the agency nor the U.S.P.C. sees a need to include exact specifications for these reference standards in the U.S.P. monograph system. Furthermore, the U.S.P. monograph system does not include exact specifications for other reference standards the U.S.P.C. provides.

The agency had a meeting with U.S.P.C. and industry representatives on May 20, 1993 (Ref. 3), to discuss the existing U.S.P. program for dentifrice reference standards and to determine if any changes were needed once the final monograph for OTC anticaries drug products is issued. Additional procedures to assure continued

availability of these dentifrice reference standards from the U.S.P.C. were developed. The U.S.P.C.'s current supply of dentifrice reference standards were subsequently tested to monitor stability (Refs. 4 through 7). Manufacturers of each reference standard have committed to retest stability every 18 months and to make every effort to resupply the U.S.P.C. with additional reference standards when supplies are depleted (Ref. 3). This should occur within 1 to 2 months after the U.S.P.C. makes a request. The U.S.P.C. will provide information concerning the reference standards' stability profile (including total fluoride, available fluoride ions, pH, and specific gravity) that is provided by each manufacturer to any purchaser upon written request. The agency believes that the availability of this information adequately addresses the comments' concerns about specifications for these dentifrice reference standards. Other information of concern, such as source of raw materials and detailed production directions, are considered confidential commercial information or trade secret information. The agency concludes that distribution of dentifrice reference standards by the U.S.P.C. is appropriate.

References

(1) The United States Pharmacopeial Convention, Inc., ''Headquarters Column,'' *Pharmacopeial Forum*, 16:3–4, 1990.

(2) The United States Pharmacopeial Convention, Inc., ''Reference Standards Catalog,'' *Pharmacopeial Forum*, 17:2458, 1991.

(3) Minutes of meeting between FDA, U.S.P.C., and industry representatives, May 20, 1993, identified as MM6, Docket No. 80N–0042, Dockets Management Branch.

(4) Comment No. RPT4, Docket No. 80N–0042, Dockets Management Branch.

(5) Comment No. RPT5, Docket No. 80N–0042, Dockets Management Branch.

(6) Comment No. RPT6, Docket No. 80N–0042, Dockets Management Branch.

(7) Comment No. RPT7, Docket No. 80N–0042, Dockets Management Branch.

44. Two comments suggested that several U.S.P. reference standards for dentifrices should be provided for each Category I fluoride ingredient and abrasive combination for which clinical proof of effectiveness has been submitted. The comments stated that the types and sources of abrasives and other ingredients present in dentifrice reference standards could have a significant effect on the results of bioavailability tests. As an example, the comments suggested that U.S.P. dentifrice reference standards for sodium fluoride products should include sodium fluoride/calcium pyrophosphate, sodium fluoride/silica, and sodium fluoride/sodium bicarbonate combinations, all of which have been proven effective in clinical trials. According to one comment, providing all of these standards would ensure the exclusion of ineffective combinations without unfairly excluding dentifrices that are effective but fail to meet the performance of an inappropriate standard.

The agency agrees with the comments that the availability of appropriate U.S.P. reference standards is essential to conduct the biological testing included in this final monograph for OTC anticaries drug products. In the tentative final monograph (53 FR 22430 at 22439), the agency stated that it was coordinating with U.S.P.C. to establish fluoride dentifrice reference standards that would be made available to manufacturers interested in manufacturing fluoride dentifrices. Subsequently, U.S.P. fluoride dentifrice reference standards have been established for Category I fluoride ingredient/abrasive combinations that had been reviewed by the Panel and determined by clinical trials to be effective anticaries drug products. These reference standards include the fluoride dentifrice combinations suggested by the comments, i.e., sodium fluoride/calcium pyrophosphate and sodium fluoride/silica, as well as sodium monofluorophosphate/calcium carbonate, sodium monofluorophosphate/dicalcium phosphate, sodium monofluorophosphate/silica, and stannous fluoride/silica (see section I.F., comment 43 of this document). A list of U.S.P. reference standards available as of the date of this final rule is on file in the Dockets Management Branch (Ref. 1).

The U.S.P. reference standards that have been established include only those dentifrice formulations that have been demonstrated to be clinically effective and that were reviewed by the Panel. At the time of the Panel's deliberation, no clinical data supporting the effectiveness of a sodium fluoride/sodium bicarbonate dentifrice were submitted for review. Consequently, a U.S.P. reference standard for this dentifrice formulation has not been established.

The agency indicated in the tentative final monograph (53 FR 22430 at 22443) that any Category I fluoride compound formulated with an appropriate abrasive can be marketed provided the dentifrice meets the biological testing requirements in § 355.70 and contains the amount of available fluoride ion stated in § 355.10. The particular fluoride ingredient contained in the chosen reference standard must be the same as the fluoride ingredient in the dentifrice formulation being tested; however, it is not necessary that the abrasive be the same as the abrasive contained in the reference standard. The agency is aware that several manufacturers use the U.S.P. reference standards, sodium fluoride/calcium pyrophosphate or sodium fluoride/silica, in the biological testing of their sodium fluoride/sodium bicarbonate dentifrice products (Ref. 2). A manufacturers' association has recently informed the agency that a new supply of one of the U.S.P. reference standards, sodium fluoride/calcium pyrophosphate (high-beta phase), will not be manufactured when the current supply at U.S.P.C. is exhausted (Ref. 3). When this sodium fluoride/calcium pyrophosphate dentifrice reference standard is no longer available, manufacturers should use the sodium fluoride/silica dentifrice reference standard in its place to conduct the biological tests. Thus, in response to the comment's suggestion that a reference standard be established for a sodium fluoride/sodium bicarbonate dentifrice, it is sufficient that the formulation meet the biological testing requirements using a reference standard containing sodium fluoride, and the available fluoride ion concentration of the dentifrice be equal to or greater than 650 ppm.

References

(1) OTC Vol. 08BTPRS, Docket No. 80N–0042, Dockets Management Branch.

(2) Memoranda of telephone conversations between C. Martin, FDA, and W. Cooley, Procter & Gamble Co., dated February 8, 1993; P. Okarma, Colgate-Palmolive Co., dated February 9, 1993; and D. Worrell, Church & Dwight Co., dated February 17, 1993, OTC Vol. 08AFM, Docket No. 80N–0042, Dockets Management Branch.

(3) Comment No. RPT4, Docket No. 80N–0042, Dockets Management Branch.

G. Comments on Package Size Limitation

45. One comment requested that the agency increase the fluoride dentifrice package size limitation from 260 mg of total fluorine per package to 350 mg to accommodate the increased amount of fluoride contained in dentifrices containing 1,500 ppm. The comment noted that dentifrice products marketed pursuant to the proposed OTC drug monograph contain less than 1,150 ppm fluoride and are marketed in 9-oz package sizes to adhere to the 260-mg total fluorine package size limitation. The comment indicated that FDA had obviously reconsidered the 260-mg dentifrice package size limitation in approving an NDA for an OTC dentifrice

product containing 1,500 ppm fluoride. According to the comment, the NDA fluoride dentifrice is marketed in 8.2 and 6.4 oz package sizes that contain 350 and 272 mg theoretical total fluorine, respectively. The comment added that these package sizes do not have any special cautionary labeling concerning the additional fluoride and do not have child-resistant closures. The comment contended that consumers would not be able to differentiate the amount of fluoride contained in packages of the 1,150-ppm and the 1,500-ppm products, and thus would not treat or use the products differently. The comment remarked that there appears to have been no concern at all that ingestion of the entire package of dentifrice was a real public safety risk. The comment concluded that consumers would benefit from an increase in the package size fluorine limitation because of the added convenience of a larger package size and more economical products on a cost per oz basis.

The comment stated that the issue in establishing a package size limitation is to prevent acute toxicity that may result from a single individual ingesting the entire contents of a fluoride dentifrice package on a single occasion, rather than to prevent the long-term adverse effects of fluoride ingestion. The comment submitted a list of 21 published animal toxicology studies (Ref. 1) that were submitted in support of the NDA for the 1,500-ppm fluoride dentifrice product. The comment stated that a review of its marketing experience records over an 18-month period (during which tubes as small as 1.4 oz were marketed) indicated that no one in the United States had ingested an entire tube of toothpaste regardless of size during that period of time. The comment added that it has marketed a 1,450-ppm fluoride (theoretical total fluorine) dentifrice extensively outside the United States in tube sizes that exceed the proposed monograph package size limitations without any special warnings or closures. The comment stated that no incidents or issues have been raised with respect to the safety of such package sizes. The comment concluded that the proposed 260-mg package size limitation is unnecessary to protect the safety or health of the American public and that the limitation should be raised to 350-mg.

After the tentative final monograph was published in 1985, the agency evaluated and approved an NDA (19–518) for an OTC fluoride dentifrice containing 1,500-ppm theoretical total fluoride (Ref. 2). As part of that evaluation, the agency reconsidered, as noted by the comment, the package size limitation of 260 mg total fluorine that had been recommended by the Panel and proposed by the agency in the tentative final monograph. The agency approved marketing of a 6.4 oz (actually containing 276 mg total fluorine) and a 8.2 oz (containing 350 mg total fluorine) package size. Since that time, the agency has reviewed the confidential sales distribution data submitted under the NDA for the extra-strength dentifrice. The data indicate extensive marketing experience for the 6.4 oz package size and limited marketing of the 8.2 oz package size. Furthermore, the manufacturer of the extra-strength dentifrice has discontinued marketing the 8.2 oz package size (Ref. 3). The agency concludes that it has insufficient marketing experience and an inadequate safety profile to support general recognition of an 8.2 oz package size containing 350 mg total fluorine per package. The agency has sufficient data to support the 6.4 oz package size of 1,500 ppm dentifrice (containing 276 mg total fluorine). Therefore, the agency is limiting monograph dentifrices to a package size containing no more than 276 mg total fluorine per package.

References

(1) Comment No. CP4, Docket No. 85N–0554, Dockets Management Branch.

(2) Copy of FDA-approved Labeling from NDA 19–518, OTC Vol. 08AFM, Docket No. 80N–0042, Dockets Management Branch.

(3) Memorandum of telephone conversation between C. Martin, FDA, and L. Cancro, Consultant to Chesebrough-Pond's Co., dated August 9, 1993, OTC Vol. 08AFM, Docket No. 80N–0042, Dockets Management Branch.

46. One comment requested that the proposed package size limitations for dentifrices, treatment rinses, and treatment gels in § 355.20(a) and (b) not be limited to 260 mg (dentifrices) and 120 mg (rinses and gels) total fluorine per package when the products are intended for professional use. Noting that the package size limitations were proposed because of potential toxicity that might be caused by accidental ingestion of these products, the comment contended that these package size restrictions are inappropriate for professional packages used by dental practitioners in their practice. The comment stated that dentists routinely administer these products to their patients as part of their treatment and, thus, require a larger container than the proposed OTC package sizes. The comment concluded that professional package sizes would have limited distribution, would not be available to consumers and, therefore, would not be a safety concern.

The package size limitations established for OTC fluoride dentifrices, treatment rinses, and preventive treatment gels in § 355.20 of this final monograph are intended for products used by the general public and not for products used only under professional supervision. The agency does not believe that safety problems will occur when a larger package size is distributed for professional office use only, provided the package is not intended to be distributed by the dentist to the consumer for home use. A product marketed in this manner would present potential safety problems similar to an OTC product. Therefore, the agency is not limiting the package size for dentifrices, treatment rinses, and preventive treatment gels labeled for professional office use only. The agency is including in § 355.60 of the monograph (professional labeling) the following statements for products marketed to health professionals in package sizes larger than those specified in § 355.20: ''For Professional Office Use Only'' and ''This product is not intended for home or unsupervised consumer use.'' For clarity, the agency is adding paragraph (a)(3) to § 355.20 as follows: ''Package size limitations do not apply to anticaries drug products marketed for professional office use only and labeled in accord with § 355.60.''

II. Summary of Significant Changes From the Proposed Rule

A. Summary of Ingredient Categories

The agency has reviewed all claimed active ingredients submitted to the Panel and to the tentative final monograph, as well as other data and information available at this time. For the convenience of the reader, the following table is a summary of the agency's categorization of OTC anticaries active ingredients.

Anticaries Active Ingredients	Monograph (M)	Nonmonograph (NM)
Hydrogen fluoride:		

Anticaries Active Ingredients	Monograph (M)	Nonmonograph (NM)
Rinse—In an appropriate formulation with 0.02 percent fluoride ion		NM
Phosphate preparations:		
Calcium sucrose phosphate		NM
Dicalcium phosphate dihydrate		NM
Disodium hydrogen phosphate		NM
Phosphoric acid		NM
Sodium dihydrogen phosphate		NM
Sodium dihydrogen phosphate monohydrate		NM
Sodium phosphate		NM
Sodium phosphate, dibasic anhydrous reagent		NM
Sodium bicarbonate		NM
Sodium fluoride:		
Dentifrice—paste: 0.188 to 0.254 percent (with ≤ 650 available fluoride ion)	M	
Dentifrice—powder: 0.188 to 0.254 percent (with ≥ 850 ppm available fluoride ion and poured-bulk density of 1.0 to 1.2 g/mL)	M	
Rinse—0.05 percent	M	
Rinse—0.02 percent	M	
Rinse—Acidulated phosphate fluoride with 0.02 percent fluoride ion	M	
Rinse—Acidulated phosphate fluoride with 0.01 percent fluoride ion	M	
Sodium fluoride and hydrogen fluoride:		
Rinse—Acidulated phosphate fluoride with 1.23 percent fluoride ion		MN
Sodium monofluorophosphate (850 to 1,150 ppm):		
Dentifrice: 0.654 to 0.884 percent (with ≥ 800 ppm available fluoride ion as $PO_3F^=$ and F^- combined)	M	
Rinse—6.0 percent		NM
Sodium monofluorophosphate (1,500 ppm):		NM
Dentifrice—1.153 percent (with ≥ 1,275 ppm available fluoride ion as $PO_3F^=$ and F^- combined)	M	
Stannous fluoride:		
Dentifrice—0.351 to 0.474 with an available fluoride ion concentration of:		
≥ 700 ppm for products containing abrasive other than calcium pyrophosphate	M	
or		
≥ 290 ppm for products containing the abrasive calcium pyrophosphate	M	
Rinse—0.1 percent	M	
Gel—0.4 percent in an anhydrous glycerin gel	M	

B. Summary of the Agency's Changes

1. The agency is revising the definitions proposed for anticaries drug, dentifrice, and treatment gel in § 355.3(c), (e), and (i), respectively. The agency is adding a definition for anhydrous glycerin in § 355.3(b), as used in § 344.3(a) (21 CFR 344.3(a)) of the final monograph for OTC topical otic drug products. Also, in § 355.3(h), the agency is adding a definition for a fluoride supplement that is intended to be swallowed. Because of these additions, proposed § 355.3(b) through (f) have been redesignated as paragraphs (c) through (g), and § 355.3(g) through (k) have been redesignated as paragraphs (i) through (m), respectively, in this final monograph. (See section I.B., comments 5, 6, and 7 of this document.)

2. The agency is including fluoride dentifrices that contain 1,500 ppm theoretical total fluorine in § 355.10(b)(2) of this final monograph. Because of concerns about dental fluorosis, the agency is requiring that dentifrices containing these fluorine concentrations be clearly labeled for use only by children 6 years of age and older and is including directions for adults and children 6 years of age and older in § 355.50(d)(1)(ii) of this final monograph. The agency is also including an optional additional labeling statement that will inform consumers of the benefits of these products. (See section I.B., comment 10 of this document.)

3. The agency is adding sodium fluoride/sodium bicarbonate powdered dentifrices in § 355.10(a)(2) of this final monograph. Directions for these products appear in § 355.50(d)(1)(iii). (See section I.B., comments 13 and 14 of this document.)

4. The agency is increasing the package size limitations in § 355.20(a) for dentifrice (toothpastes and tooth powders) packages up to 276 milligrams total fluorine per package. The agency is also adding a new paragraph in § 355.20 for fluoride powdered dentifrices that provides for tight container packaging in accordance with the definition in the U.S.P. (See section I.B., comment 15 and section I.G., comment 45 of this document.)

5. The agency notes that there is a U.S.P. monograph for Sodium Fluoride and Phosphoric Acid Topical Solution (Ref. 1). This monograph applies to acidulated phosphate sodium fluoride topical solutions having a pH between 3.0 and 4.0. Therefore, this monograph

would apply to the aqueous solution of acidulated phosphate fluoride described in § 355.10(a)(3)(ii) of the final monograph for OTC anticaries drug products and could apply to the aqueous solution of acidulated phosphate fluoride described in § 355.10(a)(3)(i) if the pH range of the U.S.P. monograph were to be expanded to 4.5. The agency and an interested manufacturer (Ref. 2) are working with U.S.P. to develop a revision in the compendial monograph for these rinse products. The agency anticipates that this revision will be completed before this final monograph for OTC anticaries drug products becomes effective. In accord with § 355.50(a) of the final monograph, manufacturers marketing these products should include the compendial name, Sodium Fluoride and Phosphoric Acid Topical Solution, as the established name in the labeling of such products.

References

(1) *The United States Pharmacopeia 23—The National Formulary 18*, United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1423, 1994.

(2) Memorandum of telephone conversation between C. Martin, FDA, and P. Okarma, Colgate-Palmolive Co., dated December 9, 1993, OTC Vol. 08AFM, Docket No. 80N–0042, Dockets Management Branch.

6. The agency is redesignating several paragraphs and is providing the following table of changes for the convenience of the reader:

Paragraph number in this final mongraph	Paragraph number in the tentative final monograph
355.3(b)	
355.3(c) through (g)	355.3(b) through (f)
355.3(h)	
355.3(i) through (m)	355.3(g) through (k)
355.10(a)(2)	
355.10(a)(3)(i)	355.10(b)(1)
355.10(a)(3)(ii)	355.10(b)(2)
355.10(a)(3)(iii)	355.10(b)(3)
355.10(a)(3)(iv)	355.10(b)(4)
355.10(a)(3)(v)	355.10(b)(5)
355.10(b)(1)	355.10(a)(2)
355.10(b)(2)	
355.10(c)(1)(i)	355.10(a)(3)
355.10(c)(1)(ii)	355.10(a)(4)
355.10(c)(2)	355.10(c)
355.10(c)(3)	355.10(b)(6)
355.20(a)(1)[1]	355.20(a)
355.20(a)(2)	355.20(b)
355.20(a)(3)	
355.20(b)	
355.50(d)(1)(i)	355.50(d)(1)(i)
355.50(d)(1)(ii)	
355.50(d)(2)(i)	355.50(d)(2)
355.50(d)(2)(ii)	
355.50(d)(2)(iii)	355.50(d)(2)(ii)
355.50(d)(5)	
355.50(e)(2)	355.50(e)(3)
355.50(f)(1)[2]	355.50(f)
355.50(f)(2)	
	355.50(g)

[1] Because § 355.20(b) has been revised, the heading of § 355.20 has been changed to ''Packaging conditions.''
[2] Because § 355.50(f)(2) has been added, the word ''statement'' in the heading of § 355.50(f) has been changed to ''statements.''

7. The agency is revising and expanding § 355.50(a) to provide the option of using the additional terms ''mouthwash,'' ''tooth powder,'' and ''tooth polish'' in the statement of identity. The agency is also requiring that the term ''preventive treatment'' be included in the statement of identity for nonabrasive fluoride gels. The agency is providing that the word ''treatment'' be optional in the statement of identity for fluoride rinse products. (See section I.C., comments 17 and 18 of this document.)

8. The agency has moved the statement ''Do not use before mixing with water'' from the warnings in proposed § 355.50(c) to the directions for use in § 355.50(d)(5) of this final monograph. This statement is to be the first sentence of the directions for concentrated treatment rinse solutions, powders, and effervescent tablets. (See section I.C., comment 26 of this document.)

9. The agency is modifying the general warning in § 330.1(g), which states: ''Keep this and all drugs out of the reach of children,'' to read as follows for fluoride dentifrice drug products: ''Keep out of the reach of children under 6 years of age.'' This warning appears in § 355.50(c)(1) of this final monograph. However, in § 355.50(c)(2), the agency continues to require the general warning in § 330.1(g) for all other OTC anticaries drug products. (See section I.B., comment 22 of this document.)

10. The agency is revising the directions for anticaries dentifrice drug products proposed in § 355.50(d) and is including the revised directions in § 355.50(d)(1)(i), (d)(1)(ii), and (d)(1)(iii)

of this final monograph. The agency is also revising the directions for use of anticaries preventive treatment gels by children in § 355.50(d) to read: ''Instruct children under 12 years of age in the use of this product (to minimize swallowing). Supervise children as necessary until capable of using without supervision.'' The agency is including the revised directions in § 355.50(d)(4) in this final monograph.

11. The agency is revising the directions for use of anticaries treatment rinses by children, proposed in § 355.50(d)(2)(i), to read: ''Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.'' The agency is including the revised directions in § 355.50(d)(2)(i) and (d)(2)(ii) in this final monograph. (See section I.C., comment 25 of this document.)

12. The agency is not including proposed § 355.50(e)(2) in this final monograph. In its place, the agency is including new § 355.55, as follows: ''*Principal display panel of all fluoride rinse drug products.* In addition to the statement of identity required in § 355.50, the following statement shall be prominently placed on the principal display panel: ′IMPORTANT: Read directions carefully before using''′. Because proposed § 355.50(e)(2) is not included in this monograph, the agency is redesignating proposed § 355.50(e)(3) as § 355.50(e)(2) in this final monograph. (See section I.C., comment 20 of this document.)

13. The agency is not including proposed § 355.50(g) (which states: ''The word ′physician′ may be substituted for the word ′doctor′ in any of the labeling statements in this section.'') in this final monograph because the agency has amended § 330.1 to permit the interchangeability of certain terms, including ''physician'' and ''doctor,'' in all OTC drug monographs. (See 59 FR 3998, January 28, 1994.)

14. The agency is modifying the introductory language in the professional labeling in § 355.60 to read: ''The labeling for anticaries fluoride treatment rinses identified in § 355.10(b) that are specially formulated so they may be swallowed (fluoride supplements) and are provided to health professionals (but not to the general public) may contain the following additional dosage information: * * *.'' (See section I.C., comment 28 of this document.)

15. The agency is including in § 355.60 (professional labeling) the following statements for products marketed to professionals in package sizes larger than those specified in § 355.20: ''For Professional Office Use Only'' and ''This product is not intended for home or unsupervised consumer use.'' The agency is also amending § 355.20 by revising paragraph (b) to read: ''Package size limitations do not apply to anticaries drug products marketed for professional office use only and labeled in accord with § 355.60.'' (See section I.G., comment 46 of this document.)

16. The agency is revising the biological testing requirements in this final monograph to require that all OTC anticaries dentifrice drug product formulations be tested in an animal caries reduction test rather than allowing this type of biological test to be optional as proposed in the tentative final monograph (53 FR 22430 at 22434). Accordingly, the first sentence in § 355.70 of the testing procedures for fluoride dentifrice drug products reads: ''A fluoride dentifrice drug product must meet the biological test requirements for animal caries reduction and one of the following tests: Enamel solubility reduction or fluoride enamel uptake.'' The agency has further revised the proposed testing guidance for parameters other than available fluoride ion and biological test requirements and is citing these revised parameters as testing intended as guidance, e.g., for use in determining expiration dating. The agency is including a revised LTP chart in the preamble of this document for informational purposes. (See section I.F., comments 37, 39, and 40 of this document.)

17. The agency is revising the testing procedures in § 355.70 to include information about the available U.S.P. fluoride dentifrice reference standards. (See section I.F., comments 43 and 44 of this document.)

III. The Agency's Final Conclusions on OTC Anticaries Drug Products

Based on available evidence, the agency is issuing a final monograph establishing conditions under which OTC anticaries drug products (aid in the prevention of dental cavities) are generally recognized as safe and effective and not misbranded. Specifically, the agency has determined that the following active ingredients meet monograph conditions: Sodium fluoride, sodium monofluorophosphate, and stannous fluoride. All other ingredients considered in this rulemaking have been determined to be nonmonograph conditions. Four of these ingredients are presently listed in § 310.545(a)(2) (21 CFR 310.545(a)(2)) as not generally recognized as safe and effective for anticaries use, i.e., hydrogen fluoride, sodium carbonate, sodium monofluorophosphate (6 percent rinse), and sodium phosphate. In this final rule, the agency is amending § 310.545(a)(2) by adding the ingredients calcium sucrose phosphate, dicalcium phosphate dihydrate, disodium hydrogen phosphate, phosphoric acid, sodium dihydrogen phosphate, sodium dihydrogen phosphate monohydrate, and sodium phosphate, dibasic anhydrous reagent to this list of nonmonograph conditions. These ingredients appear in new § 310.545(a)(2)(ii), while previous § 310.545(a)(2) is redesignated § 310.545(a)(2)(i).

The agency is removing the existing warning and caution statement required in § 369.21 (21 CFR 369.21) and exemptions for certain drugs limited by NDA's to prescription sale in § 310.201(a)(10) and (a)(15) (21 CFR 310.201(a)(10) and (a)(15)) for anticaries drug products because most portions of those regulations are superseded by the anticaries final monograph (21 CFR part 355). The items being removed include: (1) § 310.201(a)(10)(i) through (a)(10)(vi); (2) § 310.201(a)(15)(i) through (a)(15)(vi); and (3) paragraphs in § 369.21 applicable to sodium fluoride dentifrice powder and sodium monofluorophosphate dentifrice solution. The agency is reserving paragraphs (a)(10) and (a)(15) in § 310.201 for future use.

Any drug product labeled, represented, or promoted for use as an OTC anticaries drug product that contains any of the ingredients listed in § 310.545(a)(2) or that is not in conformance with the monograph (21 CFR part 355) may be considered a new drug within the meaning of section 201(p) of the act (21 U.S.C. 321(p)) and misbranded under section 502 of the act (21 U.S.C. 352) and may not be marketed for this use unless it is the subject of an approved application or abbreviated application under section 505 of the act (21 U.S.C. part 355) and part 314 of the regulations (21 CFR part 314). In appropriate circumstances, a citizen petition to amend the monograph may be submitted under 21 CFR 10.30 in lieu of an application. Any OTC anticaries drug product initially introduced or initially delivered for introduction into interstate commerce after the effective dates of § 310.545(a)(2) or the effective date of this final rule that is not in compliance with the regulations is subject to regulatory action.

An analysis of the cost and benefits of this regulation, conducted under

Executive Order 12291, was discussed in the tentative final monograph of September 30, 1985 (50 FR 39854) and in the amendment of the tentative final monograph of June 15, 1988 (53 FR 22430). No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (50 FR 39854 at 39871 and 53 FR 22430 at 22447), and the substance of that analysis has not changed. Executive Order 12291 has been superseded by Executive Order 12866. FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. All major anticaries drug products already contain monograph ingredients, and no reformulations should be necessary. This final rule will require some relabeling for these products. Manufacturers will have 1 year to implement this relabeling. Accordingly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 355

Labeling, Over-the-counter drugs.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

§ 310.201 [Amended]

2. Section 310.201 *Exemption for certain drugs limited by new-drug applications to prescription sale* is amended by removing and reserving paragraphs (a)(10) and (a)(15).

3. Section 310.545 is amended by redesignating the text of paragraph (a)(2) as paragraph (a)(2)(i); by adding new (a)(2)(i) heading and paragraphs (a)(2)(ii) and (d)(24); and by revising paragraph (d) introductory text and paragraph (d)(1) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(2) *Anticaries drug products*—(i) *Approved as of May 7, 1991.* * * *

(ii) *Approved as of October 7, 1996.*

Calcium sucrose phosphate
Dicalcium phosphate dihydrate
Disodium hydrogen phosphate[1]
Phosphoric acid[1]
Sodium dihydrogen phosphate
Sodium dihydrogen phosphate monohydrate
Sodium phosphate, dibasic anhydrous reagent[1]

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(24) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3) through (a)(4), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(9) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv), (a)(14) through (a)(15)(i), and (a)(16) through (a)(18)(i) of this section.

* * * * *

(24) October 7, 1996, for products subject to paragraph (a)(2)(ii) of this section.

4. Part 355 is added to read as follows:

PART 355—ANTICARIES DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.
355.1 Scope.
355.3 Definitions.

Subpart B—Active Ingredients

355.10 Anticaries active ingredients.
355.20 Packaging conditions.

Subpart C—Labeling

355.50 Labeling of anticaries drug products.
355.55 Principal display panel of all fluoride rinse drug products.
335.60 Professional labeling.

Subpart D—Testing Procedures

355.70 Testing procedures for fluoride dentifrice drug products.

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

Subpart A—General Provisions

§ 355.1 Scope.

(a) An over-the-counter anticaries drug product in a form suitable for topical administration to the teeth is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 355.3 Definitions.

As used in this part:

(a) *Abrasive*. Solid materials that are added to dentifrices to facilitate mechanical removal of dental plaque, debris, and stain from tooth surfaces.

(b) *Anhydrous glycerin*. An ingredient that may be prepared by heating glycerin U.S.P. at 150 C for 2 hours to drive off the moisture content.

(c) *Anticaries drug*. A drug that aids in the prevention and prophylactic treatment of dental cavities (decay, caries).

[1] These ingredients are nonmonograph except when used to prepare acidulated phosphate fluoride treatment rinses identified in § 355.10(a)(3) of this chapter.

(d) *Dental caries*. A disease of calcified tissues of teeth characterized by demineralization of the inorganic portion and destruction of the organic matrix.

(e) *Dentifrice*. An abrasive-containing dosage form for delivering an anticaries drug to the teeth.

(f) *Fluoride*. The inorganic form of the chemical element fluorine in combination with other elements.

(g) *Fluoride ion*. The negatively charged atom of the chemical element fluorine.

(h) *Fluoride supplement*. A special treatment rinse dosage form that is intended to be swallowed, and is promoted to health professionals for use in areas where the water supply contains 0 to 0.7 parts per million (ppm) fluoride ion.

(i) *Preventive treatment gel*. A dosage form for delivering an anticaries drug to the teeth. Preventive treatment gels are formulated in an anhydrous glycerin base with suitable thickening agents included to adjust viscosity. Preventive treatment gels do not contain abrasives.

(j) *Treatment rinse*. A liquid dosage form for delivering an anticaries drug to the teeth.

(k) *Treatment rinse concentrated solution*. A fluoride treatment rinse in a concentrated form to be mixed with water before using to result in the appropriate fluoride concentration specified in the monograph.

(l) *Treatment rinse effervescent tablets*. A fluoride treatment rinse prepared by adding an effervescent tablet (a concentrated solid dosage form) to water before using to result in the appropriate fluoride concentration specified in the monograph.

(m) *Treatment rinse powder*. A fluoride treatment rinse prepared by adding the powder (a concentrated solid dosage form) to water before using to result in the appropriate fluoride concentration specified in the monograph.

Subpart B—Active Ingredients

§ 355.10 Anticaries active ingredients.

The active ingredient of the product consists of any of the following when used in the concentration and dosage form established for each ingredient:

(a) *Sodium fluoride*—(1) *Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a paste dosage form*. Sodium fluoride 0.188 to 0.254 percent with an available fluoride ion concentration ≥ 650 parts per million (ppm).

(2) *Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a powdered dosage form*. Sodium fluoride 0.188 to 0.254 percent with an available fluoride ion concentration of ≥ 850 ppm for products containing the abrasive sodium bicarbonate and a poured-bulk density of 1.0 to 1.2 grams per milliliter.

(3) *Treatment rinses*. (i) An aqueous solution of acidulated phosphate fluoride derived from sodium fluoride acidulated with a mixture of sodium phosphate, monobasic, and phosphoric acid to a level of 0.1 molar phosphate ion and a pH of 3.0 to 4.5 and which yields an effective fluoride ion concentration of 0.02 percent.

(ii) An aqueous solution of acidulated phosphate fluoride derived from sodium fluoride acidulated with a mixture of sodium phosphate, dibasic, and phosphoric acid to a pH of 3.5 and which yields an effective fluoride ion concentration of 0.01 percent.

(iii) Sodium fluoride 0.02 percent aqueous solution with a pH of approximately 7.

(iv) Sodium fluoride 0.05 percent aqueous solution with a pH of approximately 7.

(v) Sodium fluoride concentrate containing adequate directions for mixing with water before using to result in a 0.02-percent or 0.05-percent aqueous solution with a pH of approximately 7.

(b) *Sodium monofluorophosphate*—(1) *Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a paste dosage form*. Sodium monofluorophosphate 0.654 to 0.884 percent with an available fluoride ion concentration (consisting of $PO_3F^=$ and F^- combined) ≥ 800 ppm.

(2) *Dentifrices containing 1,500 ppm theoretical total fluorine in a paste dosage form*. Sodium monofluorophosphate 1.153 percent with an available fluoride ion concentration (consisting of $PO_3F^=$ and F^- combined) ≥ 1,275 ppm.

(c) *Stannous fluoride*—(1) *Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a paste dosage form*. (i) Stannous fluoride 0.351 to 0.474 percent with an available fluoride ion concentration ≥ 700 ppm for products containing abrasives other than calcium pyrophosphate.

(ii) Stannous fluoride 0.351 to 0.474 percent with an available fluoride ion concentration ≥ 290 ppm for products containing the abrasive calcium pyrophosphate.

(2) *Preventive treatment gel*. Stannous fluoride 0.4 percent in an anhydrous glycerin gel, made from anhydrous glycerin and the addition of suitable thickening agents to adjust viscosity.

(3) *Treatment rinse*. Stannous fluoride concentrate marketed in a stable form and containing adequate directions for mixing with water immediately before using to result in a 0.1-percent aqueous solution.

§ 355.20 Packaging conditions.

(a) *Package size limitation*. Due to the toxicity associated with fluoride active ingredients, the following package size limitations are required for anticaries drug products:

(1) *Dentifrices*. Dentifrice (toothpastes and tooth powders) packages shall not contain more than 276 milligrams (mg) total fluorine per package.

(2) *Preventive treatment gels and treatment rinses*. Preventive treatment gel and treatment rinse packages shall not contain more than 120 mg total fluorine per package.

(3) *Exception*. Package size limitations do not apply to anticaries drug products marketed for professional office use only and labeled in accord with § 355.60.

(b) *Tight container packaging*. To minimize moisture contamination, all fluoride powdered dentifrices shall be packaged in a tight container as defined as a container that protects the contents from contamination by extraneous liquids, solids, or vapors, from loss of the article, and from efflorescence, deliquescence, or evaporation under the ordinary or customary conditions of handling, shipment, storage, and distribution, and is capable of tight reclosure.

Subpart C—Labeling

§ 355.50 Labeling of anticaries drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product as the following: ''anticavity fluoride'' (select one of the following as appropriate: ''dentifrice,'' ''toothpaste,'' ''tooth polish,'' ''tooth powder;'' (optional: ''dental'') ''preventive treatment gel;'' or (optional: ''treatment'' or ''dental'')) (select one of the following: ''rinse,'' ''concentrated solution,'' ''rinse powder,'' or ''rinse effervescent tablets''). The word ''mouthwash'' may be substituted for the word ''rinse'' in this statement of identity if the product also has a cosmetic use, as defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(i)).

(b) *Indication*. The labeling of the product states, under the heading ''Indication,'' the following: ''Aids in the prevention of dental (select one of the following: ''cavities,'' ''decay,'' ''caries (decay),'' or ''caries (cavities)''). Other truthful and nonmisleading statements, describing only the

indication for use that has been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (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.

(c) *Warning.* The labeling of the product contains the following warning under the heading ''Warning'':

(1) *For all fluoride dentifrice (toothpastes and tooth powders) products.* ''Keep out of the reach of children under 6 years of age.'' This warning shall be used in place of the first general warning statement required by § 330.1(g) of this chapter.

(2) *For all fluoride rinse and gel products.* The first general warning statement in § 330.1(g) of this chapter shall be used.

(d) *Directions.* The labeling of the product contains the following statements under the heading ''Directions'':

(1) *For anticaries dentifrice products*—(i) *Paste dosage form with a theoretical total fluorine concentration of 850 to 1,150 ppm identified in § 355.10(a)(1), (b)(1), and (c)(1).* Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

(ii) *Paste dosage form with a theoretical total fluorine concentration of 1,500 ppm identified in § 355.10(b)(2).* Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Do not use unless directed by a dentist or doctor.

(iii) *Powdered dosage form with a theoretical total fluorine concentration of 850 to 1,150 ppm identified in § 355.10(a)(2).* Adults and children 6 years of age and older: Apply powder to a wet toothbrush; completely cover all bristles. Brush for at least 30 seconds. Reapply powder as before and brush again. Rinse and spit out thoroughly. Brush teeth, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Do not use unless directed by a dentist or doctor.

(2) *For anticaries treatment rinse products*—(i) *For acidulated phosphate fluoride solution containing 0.02 percent fluoride ion, sodium fluoride 0.05 percent, sodium fluoride concentrate, and stannous fluoride concentrate identified in § 355.10(a)(3)(i), (a)(3)(iv), (a)(3)(v), and (c)(3).* Adults and children 6 years of age and older: Use once a day after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Consult a dentist or doctor.

(ii) *For acidulated phosphate fluoride solution containing 0.01 percent fluoride ion and sodium fluoride 0.02 percent aqueous solution identified in § 355.10(a)(3)(ii) and (a)(3)(iii).* Adults and children 6 years of age and older: Use twice a day after brushing your teeth with a toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: consult a dentist or doctor.

(3) *For stannous fluoride treatment rinse products.* (i) ''Use immediately after preparing the rinse.''

(ii) *For powder or effervescent tablets used to prepare treatment rinses.* ''Do not use as a rinse until all the'' (select one of the following: ''powder'' or ''tablet'') ''has dissolved.''

(4) *For anticaries preventive treatment gel products.* Adults and children 6 years of age and older: Use once a day after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink for 30 minutes after brushing. Instruct children under 12 years of age in the use of this product (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: consult a dentist or doctor.

(5) *For all concentrated treatment rinse solutions, powders, and effervescent tablets.* The following statement shall appear as the first statement under directions: ''Do not use before mixing with water.''

(e) *Additional labeling statements for anticaries drug products.* The following statements need not appear under warnings, but are required to appear on the label of anticaries drugs products as applicable.

(1) *For all preventive treatment gels.* ''This is a(n)'' (select one or both of the following: ''anticavity'' or ''fluoride'') ''preventive treatment gel, not a toothpaste. Read directions carefully before using.''

(2) *For all stannous fluoride treatment rinse, preventive treatment gel, and dentifrice products.* ''This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.''

(f) *Optional additional labeling statements*—(1) *For fluoride treatment rinses and preventive treatment gels.* The following labeling statement may appear in the required boxed area designated ''APPROVED USES'': ''The combined daily use of a fluoride preventive treatment'' (select one of the following: ''rinse'' or ''gel'') ''and a fluoride toothpaste can help reduce the incidence of dental cavities.''

(2) *For dentifrice products containing 1,500 ppm theoretical total fluorine.* ''Adults and children over 6 years of age may wish to use this extra-strength fluoride dentifrice if they reside in a nonfluoridated area or if they have a greater tendency to develop cavities.''

§ 355.55 Principal display panel of all fluoride rinse drug products.

In addition to the statement of identity required in § 355.50, the following statement shall be prominently placed on the principal display panel: ''IMPORTANT: Read directions for proper use.''

§ 355.60 Professional labeling.

(a) The labeling for anticaries fluoride treatment rinses identified in § 355.10(a)(3) and (c)(3) that are specially formulated so they may be swallowed (fluoride supplements) and are provided to health professionals (but not to the general public) may contain the following additional dosage information: Children 3 to under 14

years of age: As a supplement in areas where the water supply is nonfluoridated (less than 0.3 parts per million (ppm)), clean the teeth with a toothpaste and rinse with 5 milliliters (mL) of 0.02 percent or 10 mL of 0.01 percent fluoride ion rinse daily, then swallow. When the water supply contains 0.3 to 0.7 ppm fluoride ion, reduce the dose to 2.5 mL of 0.02 percent or 5 mL of 0.01 percent fluoride ion rinse daily.

(b) The labeling for products marketed to health to health professionals in package sizes larger than those specified in § 355.20 shall include the statements: ''For Professional Office Use Only'' and ''This product is not intended for home or unsupervised consumer use.''

Subpart D—Testing Procedures

§ 355.70 Testing procedures for fluoride dentifrice drug products.

(a) A fluoride dentifrice drug product shall meet the biological test requirements for animal caries reduction and one of the following tests: Enamel solubility reduction or fluoride enamel uptake. The testing procedures for these biological tests are labeled *Biological Testing Procedures for Fluoride Dentifrices*; these testing procedures are on file under Docket No. 80N–0042 in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and are available on request to that office.

(b) The United States Pharmacopeia fluoride dentifrice reference standards along with reference standard stability profiles (total fluoride, available fluoride ion, pH, and specific gravity) required to be used in the biological tests are available to any purchaser upon written request to the United States Pharmacopeial Convention, Inc., 1260 Twinbrook Parkway, Rockville, MD 20852.

(c) Alternative testing procedures may be used. Any proposed modification or alternative testing procedures shall be submitted as a petition in accord with § 10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative testing procedure provides results of equivalent accuracy. All information submitted will be subjected to the disclosure rules in part 20 of this chapter.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

4. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371).

§ 369.21 [Amended]

5. Section 369.21 *Drugs; warning and caution statements required by regulations* is amended by removing the entries for ''SODIUM FLUORIDE DENTIFRICE POWDER'' and ''SODIUM MONOFLUOROPHOSPHATE DENTIFRICE SOLUTION.''

Dated: September 18, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–24693 Filed 10–5–95; 8:45 am]

BILLING CODE 4160–01–F

federal register

Friday
October 6, 1995

Part III

Department of Commerce

International Trade Administration

Commerce Trade Fair Privatization: Private Sector Organization and Management of U.S. Exhibitor Pavilions in Overseas Trade Fairs; Notice

DEPARTMENT OF COMMERCE

International Trade Administration

[Docket No. 950925238–5238–01]

RIN: 0625–ZA01

Commerce Trade Fair Privatization: Private Sector Organization and Management of U.S. Exhibitor Pavilions in Overseas Trade Fairs

AGENCY: International Trade Administration, Commerce.

ACTION: Notice; request for proposals.

SUMMARY: This notice sets forth a summary of the objectives and procedures for qualified U.S. firms to assume responsibility for recruiting, promoting, organizing, and managing a U.S. exhibitor presence abroad in select overseas trade fairs which previously have been organized and managed by Commerce. In this context and throughout this notice, this transfer of responsibilities is referred to as ''privatization.''

DATES: These administrative procedures are effective October 6, 1995.

The deadline for receipt of applications from U.S. firms wishing to assume responsibility for recruitment, promotion, construction, and management of a U.S. exhibitor pavilion is November 15, 1995.

ADDRESSES: Trade Fair Certification Program, Room 2116, Export Promotion Services, International Trade Administration, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, D.C. 20230.

FOR A COPY OF THE SOLICITATION OR FOR FURTHER INFORMATION, CONTACT: Paul Bucher, U.S. Department of Commerce, Room 2116, 14th and Constitution Avenue, NW., Washington, D.C. 20230. Tel: (202) 482–1609 Fax: (202) 482–0115

Applicants also may want to contact the relevant trade fair proprietor about actual show dates, event specifics and logistics (see below).

SUPPLEMENTARY INFORMATION: In order to apply, interested firms must contact Commerce for a complete set of eligibility criteria, instructions, and an application. Applications must be received by Commerce by November 15, 1995.

The collection of information is approved by the Office of Management and Budget, OMB Control Number 0625–0222. Persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

As part of its focus to increase exports, the National Export Strategy, dated September 30, 1993, calls for the Administration to reduce the number of trade events the U.S. Government {USG} organizes, encourage more private sector participation in the trade event process, and invite qualified private sector firms to bid for those events they desire to handle. While this strategy refers to all USG-organized events, this notice is concerned only with the privatization of International Trade Administration {ITA}-organized and managed U.S. exhibitor pavilions in overseas trade shows that occur between October 1, 1996, and November 30, 1997.

As with shows under the Trade Fair Certification Program, private sector organizers in this privatization process assume the responsibilities of organizing and managing a U.S. pavilion in designated overseas trade fairs, in lieu of Commerce. Certification, via the privatization process, assures Commerce's recognition and support of these private sector efforts.

Commerce does not provide any financial assistance to organizers or to exhibitors at these shows. As with the existing Trade Fair Certification Program, the selected organizer contributes $1,500 to assist in defraying Commerce expenses incurred in supporting the organizer and exhibitors.

Organizers selected by Commerce are not representatives of the Department or the U.S. Government and are prohibited from making statements to that effect.

Principal requirements and criteria of the privatization process are summarized below:

* The applicant must be a U.S. person. A ''U.S. person'' means a U.S. citizen, or an entity (such as a corporation, partnership, association or other entity) created under the laws of the United States or of any state, or the U.S. branch or agent of a foreign person. An officer of an American Chamber of Commerce, located in the country where the applicable show is being held, is eligible to submit an application. Such an applicant must meet the same criteria and perform the same requirements as a U.S. person. Applications will not be accepted from other foreign-based persons or entities.

* In order to qualify, all applications must be received by November 15, 1995.

* Unless circumstances dictate otherwise, formation of a U.S. pavilion within the overseas fair is required.

* Production of a catalog of U.S. exhibitors is required.

* Selected organizers must recruit a minimum number of participants, which varies according to the specific event, who will display U.S. products.

* A show consisting solely of U.S. products must continue to be recruited as such. Such shows {SFO or SFW} are noted accordingly.

* Selected organizers are required to send a representative to the show for its duration and staff an office or booth within the show.

* Trade association applicants may not restrict their U.S. exhibitor recruitment campaign to association members only. Such applicants must acknowledge and agree to this condition.

* For events listed as TFOs or TFWs (trade fairs recruited by overseas' U.S. embassy staff or Washington-based Commerce staff, respectively), Commerce cannot guarantee that the foreign trade fair proprietor will agree to privatization of the U.S. pavilion in the subject event. Commerce will assist the selected U.S. pavilion organizer in its discussions with the foreign event proprietor, but it is the foreign event proprietor's decision to grant the necessary lease for exhibit space.

* Within 60 days notice of selection, the U.S. pavilion organizer must submit the necessary lease documentation.

* Pavilion organizers should note that the foreign event proprietor may opt to select its own agent in advance of Commerce's selection of a U.S. pavilion organizer. In such cases, Commerce will continue to offer its support to the U.S. pavilion organizer and event, but via the standard Trade Fair Certification Program, as prescribed in the Federal Register notice dated April 30, 1993, 58 FR 26116.

* Prior to selection of the U.S. pavilion organizer, Commerce reserves the right to withdraw an event from the privatization process if circumstances warrant Commerce's retention of the event. Also, following selection of the U.S. pavilion organizer, Commerce may withdraw its support of the U.S. pavilion organizer if Commerce determines that the U.S. pavilion organizer has not complied with the provisions outlined in this notice. Commerce also retains the option to directly organize and manage a pavilion of exhibitors under these circumstances.

* While the foreign event proprietor will be encouraged to offer the selected U.S. pavilion organizer leased space under the same conditions and rates that would be offered to Commerce, Commerce cannot guarantee it.

The appropriate Commerce Officer should be contacted to discuss Commerce's activities and responsibilities as they relate to the U.S. pavilion in that particular show. Commerce seeks applications from qualified firms, associations, or

American Chambers of Commerce abroad to assume U.S. pavilion recruitment, promotion, organization and management functions in the following overseas trade fairs:

City/country	Industry	Event name	Date	Type	Ex. No.
Poznan, Poland Barbara Grabowska Commercial Assistant U.S. & Foreign Commercial Service U.S. Trade Center Warsaw Unit 1340 APO AE 09213–1340 Tel: 48–2–621–4515; 621–4216; 625–4300 Fax: 48–2–621–6327	Agricultural machinery amd Equipment	Polagra	Oct–96	TFO	20
Prague, Czech Rep. Kathleen Kriger Commercial Officer U.S. and Foreign Commercial Service U.S. Embassy Prague Unit 1330 APO AE 09213–1330 Tel: 42–2–2421–9844 Fax: 42–2–2421–9965	Medical Instruments, equipment and supplies	MEFA	Oct–96	TFO	15
Perth, Australia Amy Niesporek U.S. and Foreign Commercial Service U.S. Consulate Sydney PSC 280, Unit 11026 APO AP 96554–0002 Tel: 61–2–373–9200 Fax: 61–2–221–0573	Oil and gas field machinery	PTA-Petroleum	Oct–96	TFO	17
Bucharest, Romania William Crawford Senior Commercial Officer U.S. and Foreign Commercial Service U.S. Embassy Bucharest Unit 1315 APO AE 09213–1315 Tel: 40–1–210–4042; 210–0149 Fax: 40–1–210–0395	General industrial equip.	Bucharest international fair	Oct–96	TFO	30
New Delhi, India Shantanu Mitra Commercial Specialist U.S. and Foreign Commercial Service U.S. Embassy New Delhi Shanti Path, Chanakyapuri 110021 New Delhi, India Tel: 91–11–600651 Fax: 91–11–687–2391	Process controls, instrumentation	Indian engineering fair	Feb–97	TFO	20
Cairo, Egypt Laron Jensen Senior Commercial Officer U.S. and Foreign Commercial Service U.S. Embassy Cairo APO AE 09839–4900 Tel: 20–2–355–7371 Fax: 20–2–355–8368	General industrial equip.	Cairo int'l fair	Mar–97	TFO	35
Casablanca, Morocco Latifa Louraqui Commercial Specialist U.S. and Foreign Commercial Service U.S. Consulate Casablanca APO AE 09718 (CAS) Tel: 212–2–26–45–50 Fax: 212–2–22–02–59	Computers and telecommunications	SITEB	Apr–97	TFO	15
Brussels, Belgium Nicole Pollet Commercial Specialist U.S. and Foreign Commercial Service U.S. Embassy Brussels PSC 82, Box 002 APO AE 09724 Tel: 32–2–508–2111	Telecommunications equipment	Telecomm Brussels	May–97	TFO	15

City/country	Industry	Event name	Date	Type	Ex. No.
Fax: 32–2–512–6653					
Tel Aviv, Israel Elana Shelemay Commercial Assistant U.S. and Foreign Commercial Service U.S. Embassy Tel Aviv PSC 98, Box 100 APO AE 09830 Tel: 972–3–517–6161 Fax: 972–3–510–7215	High technology goods	Technology	May–97	TFO	20
Sao Paulo, Brazil Eduardo Altenfelder Commercial Specialist U.S. and Foreign Commercial Service Rua Estados Unidos, 1812 Sao Paulo, S.P. 01427–002 Brazil Tel: 55–11–853–2011/2411/2778 Fax: 55–11–853–2744	Food processing and packaging machinery	FISPAL	Jun–97	TFO	20
Santo Domingo, Dominican Republic Robert Bucalo Senior Commercial Officer U.S. and Foreign Commercial Service U.S. Embassy Santo Domingo Unit 5500 APO AA 34041 Tel: 809–221–2171 Fax: 809–688–4838	General industrial equip. and consumer goods	EXPO USA	JUN–97	SFO	60
Barcelona, Spain Dorothy Lutter Commercial Officer U.S. and Foreign Commercial Service U.S. Consulate Barcelona PSC 61, Box 0005 APO AE 09642 Tel: 34–3–280–2227 Fax: 34–3–205–7705	Telecommunications	FERCOM	Oct–97	TFO	15
Basel, Switzerland Werner Wiedmer Commercial Specialist U.S. and Foreign Commercial Service U.S. Embassy Bern Jubilaeumstrasse 93 3005 Bern Switzerland Tel: 41–31–357–7011 Fax: 41–31–357–7336	Hotel and restaurant	IGEHO	Nov–97	TFO	15

SHOW TYPE:
- TFO Trade Fair recruited by Commerce staff overseas.
- SFO Trade Fair for U.S. products/services only (recruited by overseas post).
- TFW Trade Fair recruited by Washington-based Commerce staff.

Ex. No. The minimum number of firms exclusively exhibiting U.S. products or services to be recruited.

Dated: September 29, 1995.

Mary Fran Kirchner,

Chairman, ITA Trade Events Board.

[FR Doc. 95–24879 Filed 10–5–95; 8:45 am]

BILLING CODE 3510–FP–P

federal register

Friday
October 6, 1995

Part IV

Office of Management and Budget

Cost Principles for Non-Profit Organizations; Notices

OFFICE OF MANAGEMENT AND BUDGET

Cost Principles for Non-Profit Organizations; Final Revision to Provision on Interest Allowability

AGENCY: Office of Management and Budget.

ACTION: Final revision to the interest provision in OMB Circular A–122, ''Cost Principles for Non-Profit Organizations''.

SUMMARY: This notice finalizes a revision to the provision on interest allowability for non-profit organizations.

EFFECTIVE DATE: The revision is effective on September 29, 1995.

FOR FURTHER INFORMATION CONTACT: Federal agencies should contact the Office of Federal Financial Management, Office of Management and Budget, (202) 395–3993. Non-Federal organizations should contact the organization's cognizant Federal funding agency. For a copy of the Circular, contact Office of Administration, Publications Office, Room 2200, New Executive Office Building, Washington, DC 20503, or telephone (202) 395–7332.

SUPPLEMENTARY INFORMATION:

A. Background

On September 26, 1994, the Office of Management and Budget (OMB) published a proposed revision to OMB Circular A–122, ''Cost Principles for Non-Profit Organizations,'' in the Federal Register (59 FR 49090). The proposed revision was intended to encourage non-profit organizations to acquire, whether by lease or purchase, assets in the manner that would be least expensive. It provided that interest on buildings and equipment would be allowable under certain circumstances which included a favorable lease/purchase analysis, a limit on the interest rate, an offsetting of certain investment earnings against interest costs, and a needs assessment which might require pre-approval. By allowing for reimbursement of interest, OMB anticipated that many non-profit organizations would be able to enter into purchase financing arrangements which could result in long- and/or short-term savings when compared to leasing alternatives.

OMB received approximately 150 letters during the 60-day comment period from non-profit organizations, auditing firms, and government agencies. The comments were all supportive of the revision to allow interest, although some requested modifications to the criteria or clarifications regarding various aspects of the revision. As a result, as explained below, OMB has adopted the proposal with modifications.

The revision will serve to provide consistency on interest allowability across OMB's three cost principles circulars (Circular A–122; Circular A–21, ''Cost Principles for Educational Institutions;'' and Circular A–87, ''Cost Principles for State, Local and Indian Tribal Governments'') and to reduce the cost to the Federal Government of non-profit organizations' facilities.

OMB is committed to providing consistency across the three cost principles circulars with regard to cost allowability, and also to ensure that facilities cost reimbursements are reasonable and economical. Accordingly, we are hereby providing notice that efforts to establish benchmark payment rates for space used to support federally-sponsored research agreements will include both the non-profit community as well as the university community (as announced in the Federal Register (60 FR 7105) on February 6, 1995, in a proposed revision to Circular A–21). This benchmarking effort has been identified as a possible superior, long-range alternative to the needs justification being imposed by this revision to Circular A–122. If adopted, the benchmarks would eventually replace the needs justification and would form the basis for reimbursement for research space used in the conduct of federally-sponsored research.

With this final revision, Circular A–122 consists of the Circular as issued in 1980 (45 FR 46022; July 8, 1980), as amended in 1984 (49 FR 18260; April 27, 1984), in 1987 (52 FR 19788; May 27, 1987), and in this notice.

B. Comments and Responses

The comments received and OMB responses are summarized below.

Needs Assessment

Comment: The proposal would place restrictions and requirements on non-profit organizations under sponsored agreements that are not placed on commercial organizations under contracts with the Federal Government.

Response: It is true that commercial organizations with Federal contracts do not have some of the requirements, such as justifying the need for an asset, that are being applied to non-profit organizations under this revision to Circular A–122. As OMB explained in the September 1994 proposal (59 FR 49090), the Federal Government often contributes a substantial share of a non-profit organization's revenues, and this greater Federal share could decrease the incentives for non-profit organizations to make the most economical lease/purchase decisions. The requirements in the proposal were deemed to be reasonable methods of ensuring that reimbursements to non-profit organizations will be at appropriate levels. Threshold levels for these requirements were established in the final revision to reduce the paperwork burden on smaller asset purchases. Finally, it is more appropriate to compare the restrictions on non-profit organizations to those being proposed for universities under Circular A–21 (60 FR 7105), which are similar to those being instituted by this revision to Circular A–122.

Comment: Needs assessment criteria are not needed because non-profit organizations already have incentives to operate in a cost-efficient manner. To imply otherwise, mischaracterizes the funding situations faced by non-profit organizations and is factually incorrect. Also, no criteria were listed for a needs assessment. Further, the pre-approval provision will cause delays and be a resource drain on Federal agencies, short on manpower and expertise to evaluate the needs analyses, and would create confusion with the ''after-the-fact'' reviews that could result in disapproval.

Response: The ''needs assessment'' was re-termed ''needs justification,'' and is required to be prepared only for the acquisition of facilities costing over $10 million and for which the Federal Government's reimbursement is expected to equal or exceed 40 percent of the facility's cost. (The 51 percent proposed was reduced to 40 percent because of the significance of the Federal Government's investment in facilities.) The needs justification will simply provide a formal mechanism for organizations to justify their need for the facility, a significant percentage of which is being financed with Federal dollars. This justification is implicit under other provisions of Circular A–122 on excess capacity, allocability, etc. (Attachment A, A.2 and A.3; Attachment B.16). Criteria for the needs justification are specified in the revision, and OMB believes the criteria will parallel any such justification that a non-profit organization's management and board of directors would be expected to use in determining the need for additional facilities. Therefore, the needs justification would not create an administrative burden for the organization. The pre-approval aspect of the needs justification has been eliminated for many of the reasons cited

by the commentor. The requirement now calls for the preparation, rather than the submission, of the needs justification.

OMB is concerned about ensuring that costs reimbursed by the Federal Government are not excessive, as might be the case if an organization built a more expensive class A building when a less expensive class B building would suffice. Therefore, the concept of benchmark payment rates for space costs under Circulars A–122 and A–21 is being addressed by an interagency task force. Benchmarking recommendations and proposals made by this task force will be addressed in a future OMB notice to be proposed in the Federal Register. If and when the benchmark payment rates for space costs are established, OMB anticipates that the requirement for a needs justification would be eliminated.

Lease/Purchase Analysis

Comment: A lease/purchase analysis is unnecessary and potentially expensive to a non-profit organization. Lease/purchase analyses should be required only for assets costing in excess of $1 million.

Response: Lease/purchase analyses generally are performed by an organization's management as a common business practice in order to determine the costs of acquisition of expensive assets under various scenarios. Such analyses normally would be performed whether or not Federal funds are at issue, and are not expensive analysis to perform, certainly when one considers the amounts that are at stake in a real estate lease or purchase. Also, by identifying less expensive acquisition alternatives, such analyses generally pay for themselves. Circular A–122 requires that to be allowable, costs must be reasonable (Attachment A, A.3), and a lease/purchase analysis will provide such supporting documentation. However, OMB recognizes that a lease/purchase analysis may not be cost-effective for smaller facilities acquisitions. Therefore a threshold of $500,000 was established in the final revision for the lease/purchase analysis requirement for facilities. There will be no requirement for a lease/purchase analysis for equipment.

Comment: Lease/purchase analysis is arbitrary because 30–40 year leases do not generally exist for comparison to purchases.

Response: It is true that 30–40 year leases do not generally exist for comparison purposes. However, potential long term lease costs can be estimated for purposes of comparison with purchasing as an acquisition alternative. This is a common business practice for private sector companies, which must decide whether to purchase or lease the office, warehouse, or factory space they need. These estimates must be made in order to provide a comparison from which to determine the least costly alternative.

Comment: A non-profit organization should be allowed to recover interest in those circumstances when purchasing is clearly justified for management or programmatic reasons (such as when the grantee wishes to expand an existing, owned facility) or when leasing on site is not practical or is not legally permissible.

Response: OMB understands that there may be circumstances which would cause a non-profit organization to purchase an asset using debt financing even though it may be more expensive than leasing, regardless of the criteria established in this Circular. In that event, the provision at paragraph 19.a.(1)(e) does not prohibit an asset purchase, but it does limit reimbursement to the amount under the least expensive alternative, even if the organization pursues a more expensive alternative. A lease/purchase analysis is not required for renovations or alteration under Paragraph 19.a.(1)(b).

Comment: The Circular should clarify whether or not interest on land is allowable, and whether or not currently-owned land can be considered an equity contribution in a building project.

Response: It is OMB's intent that interest on land would be allowable (See Attachment B, Section 19.a.(1)). (The cost of land continues to be unallowable under Attachment B.9.c(1).) To treat interest on financing for land as an unallowable cost could otherwise skew the result of a lease/purchase analysis. Equity in currently-owned land may be considered an equity contribution to a project. Valuation of the land for purposes of determining the amount of equity shall be in accordance with OMB Circular A-110, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations,'' Subpart C, paragraph _____.23(c). For the purposes of the interest provision of Circular A–122, equity contributions may be any non-Federal contribution.

Comment: The proposal references OMB Circular A–94, ''Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs,'' which does not apply to many non-profit organizations, and could increase costs. Also, the application of the discount rate and the present value of money calculation in the lease/purchase analysis are unnecessary and serve merely to complicate the assessment.

Response: Discount rates are commonly used in private sector lease/purchase analysis calculations of cash flows discounted for the time value of money. The provisions of Section 19.a.(1)(b) of this revision will assist in providing consistency in the calculation methodologies and discount rates used by non-profit organizations performing lease/purchase analyses. The reference to Circular A–94 has been omitted in the final revision, although the concepts of net present value found in Circular A–94 were incorporated into the final revision. Present value concepts are necessary for appropriate analysis in order to evaluate the effects of the time value of money.

Comment: The Circular should provide policy guidance to assure comparability of assumptions used in the preparation of the lease/purchase analysis.

Response: The proposal was modified to provide clarification and consistency in the preparation of the lease/purchase analysis at Paragraph 19.a.(1)(b).

Cash Flow Analysis

Comment: The ''excess cash flow'' requirements are unfair to non-profit organizations which carry all of the risk associated with purchasing a facility, while the Federal Government is at no risk. Over time, depreciation and principal payments will be equal, but a penalty on ''excess cash flow'' would result in the Federal Government's paying for less than the full cost of the use of a facility. This treatment provides incentives to lease rather than to own.

Response: The excess cash flow provisions are not related to risk of ownership, but to excessive earnings on the cash flow from allowable costs. This provision does not result in the Federal Government's paying for less than its allocable share of the allowable cost of a facility. The Federal Government will pay its allocable share of applicable interest depending upon the use of the capital asset to support Federal projects. The interest on excess cash flows simply minimizes the interest cost to the Federal Government in instances where cash flow from depreciation reimbursement exceeds debt principal payments. In order to reduce the administrative and paperwork burden on smaller acquisitions, this revision only requires interest to be calculated on excess cash flows related to debt instruments of $1 million or more, when the initial equity contribution is less than 25 percent.

Comment: The provision requires that earnings on positive cash flows be offset against interest expense. If principal payments include the cost of land, the positive cash flow and imputed earnings will be understated.

Response: The commentor is correct. Because the cost of land is unallowable (as opposed to the allowable cost of interest on land, as explained above) under Attachment B Section 9.c(1), when computing cash flows, each debt principal payment must be reduced by an amount equal to the portion of the principal payment attributable to land. The wording of the provision has been revised (Attachment B, Section 19.a.(1)(f)(ii)) to clarify how cash flow analyses are to be prepared.

Comment: The provision does not recognize the cost of the non-profit organization's capital, or equity, that is contributed to the asset acquisition, thus reducing the financing needs.

Response: In computing cash flow under Attachment B, Paragraph 19.a.(1)(f)(ii), the non-profit organization's equity contribution, regardless of the amount, is recognized and treated as an outflow along with principal and interest payments. This treatment has the effect of allowing the grantee to retain earnings on positive cash flows attributable to its equity capital. If the organization's equity contribution exceeds 25 percent, a cash flow analysis is not required and interest earnings on positive cash flow are not required to be offset against interest expense charged to Federal programs. OMB intends to study allowing the cost of an organization's own capital for consideration in future revisions to Circular A–122. OMB may also consider other alternatives to reimburse facilities costs. If and when alternative facilities reimbursement methods are developed and considered to be potentially superior to the present method, they will be published for comment in the Federal Register.

Comment: The provision will require Federal agencies to compute earnings on positive cash flows. How and at what rate is this to be performed?

Response: The provision was modified at Paragraph 19.a.(1)(f)(ii) to clarify when and how earnings are to be computed. (The three month Treasury Bill rate to be used in the calculations can be found in such publications as the *Wall Street Journal*.) OMB has developed a sample format for reporting excess cash flows, which is displayed as follows:

BILLING CODE 3110–01–P

A-122 Excess Cash Flow Calculation
Sample Format for Annual Report -- Applicable for debt arrangements over $1 million, unless initial equity contribution equals 25% or more

Year ____ of ____ Years		Month 1	2	3	4	.....	12	Annual Total
Line 1	Prior period's cumulative cash flow balance (Prior Month's or Year's Line 9)							
	Add this period's inflows:							
Line 2	Depreciation expense (Note 1)							
Line 3	Interest expense (Note 2)							
Line 4	Amortization of debt issuance costs (Note 2)							
	Subtract this period's outflows:							
Line 5	Principal payments (Note 3)							
Line 6	Interest payments (Note 3)							
Line 7	Subtotal of cumulative cash flows (Line 1+2+3+4-5-6)							
Line 8	In initial period only, subtract initial equity contribution(Note 4) (Will be zero after initial period)							
Line 9	Total of cumulative cash flows (In initial period, Line 7 - Line 8) (In subsequent periods, equals Line 7)							
Line 10	If line 9 is positive, state month's closing interest rate on 3-month Treasury Bill If line 9 is negative, put "0" (zero)							
Line 11	Imputed interest income on cumulative positive cash flow Monthly columns = (Line 10 x Line 9)/12							
Line 12	Allowable interest for period (Line 6 - Line 11)							

Note 1: May include amortization of capitalized construction interest in accordance with GAAP. Depreciation expenses should be reported on a monthly basis (Annual expense/12).

Note 2: Interest expense and amortization of debt issuance costs that are not included in loan amount should be reported on a monthly basis (Annual expense/12).

Note 3: If land is included in the financing arrangement, Line 5 would be calculated as: principal payment - (Debt proceeds used to purchase land / total debt proceeds x principal payment). Principal and interest payments should be reported in the month that payments were made.

Note 4: This line may only include amounts of initial equity contribution made prior to occupancy of the facility. The amount is to be entered only in the initial period covered by the cash flow submission, and should be left blank in future periods.

Other

Comment: Definitions for a number of terms should be included, e.g., equity contribution, re-acquired assets, and asset cost.

Response: Definitions of terms have been added to the final revision in Attachment B, Paragraph 19.a.(3).

Comment: The provision should provide a disclaimer of the Federal Government's liability regarding the debt incurred by a non-profit organization when financing assets to be used in the fulfillment of sponsored agreements.

Response: OMB does not express or imply any long-term obligation on the part of the Federal Government to continue or increase funding for sponsored agreements covered by this Circular. Nor does it express or imply any obligation or liability to a non-profit organization or any third party with respect to any financial borrowing or other financing arrangement entered into by a non-profit organization to purchase an asset.

Comment: Excess capacity costs should be unallowable, with a one year grace period.

Response: The costs of initial excess capacity are unallowable under the allocability and allowability provisions of this Circular found at Attachment A, Paragraph 2.a and Attachment B, Paragraph 16 which do not allow exceptions for excess capacity in newly-acquired space.

Comment: Interest costs of fully depreciated assets should also be unallowable.

Response: Under the allocability provision found at Attachment A, Paragraph 2.a, the interest costs on fully-depreciated, retired, scrapped, or non-existent assets are unallowable.

Comment: In the best interests of the Federal Government, the provision should allow for the prior existence of special agreements which already allowed interest.

Response: OMB does not intend for the revision to replace any written agreements between non-profit organizations and the Federal Government that were made prior to the effective date of this revision.

Comment: Professional fees associated with the purchase of real property should be allowable.

Response: Usual and customary professional fees and related costs and fees associated with, and necessary to, the acquisition of real property are allowable under Attachment B, Paragraph 9 whether expensed or capitalized, in accordance with Generally Accepted Accounting Principles (GAAP).

Comment: Many non-profit organizations are being forced to decide on debt-financed property purchases before the change to Circular A–122 is adopted. The rule should have a retroactive date and/or allow interest incurred after the effective date, regardless of the asset acquisition date if the criteria set forth are met.

Response: If interest were to be allowed on assets purchased before the effective date of this revision, the Federal Government would incur the substantial cost on debt arrangements entered into by non-profit organizations with full knowledge that interest was an unallowable cost. In addition, these prior purchases were obviously not made in accordance with the requirements that are being announced here. Also, changes to interest allowability under Circulars A–21 and A–87 have, similarly, not been applied retroactively.

Comment: The substantial relocation provision raises more issues than it solves and is inconsistent with Executive Order 12866 calling for streamlined regulations. Also, it suggests that the Federal Government is in a better position than the non-profit organization to make relocation decisions. If retained, the substantial relocation provision should be limited to 20 years.

Response: The substantial relocation provision at Attachment B, Paragraph 19.a.(1)(f)(iii) exists to ensure that the location of Federal program operations is not shifted unnecessarily, or ''churned,'' to other debt-financed facilities after a debt instrument is substantially retired. By churning Federal programs into debt-financed buildings, the Federal Government carries the burden of costs of facilities expansion that should reasonably be shared with non-Federal entities. If such a relocation is needed, the cognizant Federal agency must be notified and an adjustment of the indirect cost rate may be necessary. The relocation does not require approval of the Federal cognizant agency, as was originally proposed. (However, if interest will be claimed on the new location, then the provisions of Paragraph 19.a. apply.) A time limit of 20 years was added to this provision.

Comment: The provision should cover financing of alterations and renovations.

Response: The provision was modified at Attachment B, Paragraph 19.a.(1) to clarify the allowability of interest on financing of alterations and renovations. Alterations and renovations will not require a needs justification.

Comment: The provision should clarify whether ''re-acquired assets'' include replacement assets.

Response: The provision was modified at Paragraph 19.a.(1) to clarify the allowability of interest on replacement assets. However, interest will not be allowable for re-acquired assets (Paragraph 19.a.(1)(f)(i)).

Comment: ''Fair market interest rate'' should be qualified to similarly-situated organizations borrowing from a third party.

Response: The provision was modified at Paragraph 19.a.(1)(b) to limit reimbursement to the fair market borrowing rates available to the organization from an unrelated (''arm's length'') third party. This provision is intended to prevent the Federal Government from reimbursing organizations for interest at higher rates than necessary.

Comment: The provision should address situations of leasing and buying to/from related parties.

Response: The revision eliminates the profit in related party transactions by limiting interest expense reimbursement to a rate no higher than available from an unrelated third party (Attachment B, Paragraph 19.a.(1)(c)) and by limiting allowable costs related to the purchase price of assets to the fair market value available from an unrelated third party (Attachment B, Paragraph 19.a.(1)(f)(iv)). Also, Attachment B, Paragraph 42.c. of the Circular provides that ''Rental cost under less-than-arms-length leases are allowable only up to the amount that would be allowed had title to the property vested in the organization.''

Comment: The provision should state that interest on capital leases is allowable.

Response: The provision was modified at Attachment B, Paragraph 19.a.(1) to clarify the allowability of interest under capital leases, but a revised Attachment B, Paragraph 42.d. limits reimbursement to the allowable costs of ownership, such as depreciation, maintenance, taxes, and insurance. Unallowable costs include amounts paid for profit, management fees, and taxes that would not have been incurred had the organization purchased the facility. To satisfy the lease/purchase analysis requirement, an analysis could be prepared to compare either the costs of an operating lease versus a capital lease, or a capital lease versus a purchase.

Comment: The provision should clarify that adjustable rate financing methods are acceptable.

Response: OMB does not prescribe the form that borrowing arrangements must take in order to be allowable. Therefore,

the provision allows interest regardless of whether interest rates are fixed or variable, but assumes that the rates are market rates.

Comment: The proposed wording results in an unintended effective restriction upon debt structures with variable or deferred repayment terms, such as balloon loans.

Response: The provision is not intended to restrict the structuring of debt repayment arrangements. However, it is designed to minimize cost to the Federal Government where principal payments are delayed, thus increasing interest costs. Under a balloon payment arrangement, interest is charged on the full amount of the principal for the full term of the loan. In order to reduce the interest costs that the Federal grants will be charged, the revision has the effect of encouraging debt structures where the principal is paid down on a regular basis.

Comment: The Circular does not specify whether predetermined multiple-year indirect cost rates can be established for non-profit organizations that incur interest costs for capital assets since the Federal participation of space in the new facility may vary from year to year.

Response: Predetermined multiple-year indirect cost rates can be established for non-profit organizations if the Federal cost negotiators can determine the reasonableness and acceptability of space projections provided by the non-profit organizations, regardless of whether interest costs are incurred in financing the asset.

Alice M. Rivlin,

Director.

Revisions to Attachment B of Circular A–122

The following paragraphs replace paragraph 19.a of Attachment B to Circular A–122:

19. Interest, fundraising, and investment management costs.

a. Interest.

(1) Costs incurred for interest on borrowed capital or temporary use of endowment funds, however represented, are unallowable. However, interest on debt incurred after the effective date of this revision to acquire or replace capital assets (including renovations, alterations, equipment, land, and capital assets acquired through capital leases), acquired after the effective date of this revision and used in support of sponsored agreements is allowable provided that:

(a) For facilities acquisitions (excluding renovations and alterations) costing over $10 million where the Federal Government's reimbursement is expected to equal or exceed 40 percent of an asset's cost, the non-profit organization prepares, prior to the acquisition or replacement of the capital asset(s), a justification that demonstrates the need for the facility in the conduct of federally-sponsored activities. Upon request, the needs justification must be provided to the Federal agency with cost cognizance authority as a prerequisite to the continued allowability of interest on debt and depreciation related to the facility.

The needs justification for the acquisition of a facility should include, at a minimum, the following:

- A statement of purpose and justification for facility acquisition or replacement
- A statement as to why current facilities are not adequate
- A statement of planned future use of the facility
- A description of the financing agreement to be arranged for the facility
- A summary of the building contract with estimated cost information and statement of source and use of funds
- A schedule of planned occupancy dates

(b) For facilities costing over $500,000, the non-profit organization prepares, prior to the acquisition or replacement of the facility, a lease/purchase analysis in accordance with the provisions of OMB Circular A–110, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations,'' sections _____.31 through _____.37, which shows that a financed purchase or capital lease is less costly to the organization than other leasing alternatives, on a net present value basis. Discount rates used should be equal to the non-profit organization's anticipated interest rates and should be no higher than the fair market rate available to the non-profit organization from an unrelated (''arm's length'') third-party. The lease/purchase analysis shall include a comparison of the net present value of the projected total cost comparisons of both alternatives over the period the asset is expected to be used by the non-profit organization. The cost comparisons associated with purchasing the facility shall include the estimated purchase price, anticipated operating and maintenance costs (including property taxes, if applicable) not included in the debt financing, less any estimated asset salvage value at the end of the period defined above. The cost comparison for a capital lease shall include the estimated total lease payments, any estimated bargain purchase option, operating and maintenance costs, and taxes not included in the capital leasing arrangement, less any estimated credits due under the lease at the end of the period defined above. Projected operating lease costs shall be based on the anticipated cost of leasing comparable facilities at fair market rates under rental agreements that would be renewed or reestablished over the period defined above, and any expected maintenance costs and allowable property taxes to be borne by the non-profit organization directly or as part of the lease arrangement.

(c) The actual interest cost claimed is predicated upon interest rates that are no higher than the fair market rate available to the non-profit organization from an unrelated (''arm's length'') third party.

(d) Investment earnings, including interest income, on bond or loan principal, pending payment of the construction or acquisition costs, are used to offset allowable interest cost. Arbitrage earnings reportable to the Internal Revenue Service are not required to be offset against allowable interest costs.

(e) Reimbursements are limited to the least costly alternative based on the total cost analysis required under (b). For example, if an operating lease is determined to be less costly than purchasing through debt financing, then reimbursement is limited to the amount determined if leasing had been used. In all cases where a lease/purchase analysis is performed, Federal reimbursement shall be based upon the least expensive alternative.

(f) Non-profit organizations are also subject to the following conditions:

(i) Interest on debt incurred to finance or refinance assets acquired before or reacquired after the effective date of this Circular is not allowable.

(ii) For debt arrangements over $1 million, unless the non-profit organization makes an initial equity contribution to the asset purchase of 25 percent or more, non-profit organizations shall reduce claims for interest expense by an amount equal to imputed interest earnings on excess cash flow, which is to be calculated as follows. Annually, non-profit organizations shall prepare a cumulative (from the inception of the project) report of monthly cash flows that includes inflows and outflows, regardless of the funding source. Inflows consist of depreciation expense, amortization of capitalized construction interest, and annual interest expense. For cash flow calculations, the annual inflow figures shall be divided by the number of

months in the year (usually 12) that the building is in service for monthly amounts. Outflows consist of initial equity contributions, debt principal payments (less the pro rata share attributable to the unallowable costs of land) and interest payments. Where cumulative inflows exceed cumulative outflows, interest shall be calculated on the excess inflows for that period and be treated as a reduction to allowable interest expense. The rate of interest to be used to compute earnings on excess cash flows shall be the three month Treasury Bill closing rate as of the last business day of that month.

(iii) Substantial relocation of federally-sponsored activities from a facility financed by indebtedness, the cost of which was funded in whole or part through Federal reimbursements, to another facility prior to the expiration of a period of 20 years requires notice to the Federal cognizant agency. The extent of the relocation, the amount of the Federal participation in the financing, and the depreciation and interest charged to date may require negotiation and/or downward adjustments of replacement space charged to Federal programs in the future.

(iv) The allowable costs to acquire facilities and equipment are limited to a fair market value available to the non-profit organization from an unrelated (''arm's length'') third party.

(2) For non-profit organizations subject to ''full coverage'' under the Cost Accounting Standards (CAS) as defined at 48 CFR 9903.201, the interest allowability provisions of paragraph 19.a. do not apply. Instead, these organizations' sponsored agreements are subject to CAS 414 (48 CFR 9903.414), cost of money as an element of the cost of facilities capital, and CAS 417 (48 CFR 9903.417), cost of money as an element of the cost of capital assets under construction.

(3) The following definitions are to be used for purposes of paragraph 19:

(a) ''Re-acquired assets'' means assets held by the non-profit organization prior to the effective date of this revision that have again come to be held by the organization, whether through repurchase or refinancing. It does not include assets acquired to replace older assets.

(b) ''Initial equity contribution'' means the amount or value of contributions made by non-Federal entities for the acquisition of the asset or prior to occupancy of facilities.

(c) ''Asset costs'' means the capitalizable costs of an asset, including construction costs, acquisition costs, and other such costs capitalized in accordance with General Accepted Accounting Principles (GAAP).

The following paragraph replaces paragraph 42.d. of Attachment B to Circular A–122):

42. Rental Costs.

d. Rental costs under leases which are required to be treated as capital leases under Generally Accepted Accounting Principles (GAAP), are allowable only up to the amount that would be allowed had the organization purchased the property on the date the lease agreement was executed, i.e., to the amount that minimally would pay for depreciation or use allowances, maintenance, taxes, and insurance. Interest costs related to capitalized leases are allowable to the extent they meet criteria in Attachment B, paragraph 19.a. Unallowable costs include amounts paid for profit, management fees, and taxes that would not have been incurred had the organization purchased the facility.

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OFFICE OF MANAGEMENT AND BUDGET

Cost Principles for Non-Profit Organizations; Proposed Revisions

AGENCY: Office of Management and Budget.

ACTION: Proposed revisions to OMB Circular A–122, ''Cost Principles for Non-Profit Organizations''.

SUMMARY: This notice proposes changes to OMB Circular A–122, ''Cost Principles for Non-Profit Organizations,'' to revise the definition of equipment, to make certain additional costs unallowable, to modify the multiple allocation base method for computing indirect cost rate(s), and to place a ceiling on the administrative portion of indirect costs for organizations with Federal funding over $10 million. The proposed changes provide consistency across OMB's cost principles Circulars A–122; A–87, ''Cost Principles for State and Local Governments;'' and A–21, ''Cost Principles for Educational Institutions.''

DATES: Comments on these proposals are due December 5, 1995.

ADDRESSES: Comments should be mailed to Financial Standards and Reporting Branch, Office of Federal Financial Management, Office of Management and Budget, 725 17th Street, N.W., Room 6025, Washington, DC 20503. Comments up to three pages in length may be submitted via facsimile to 202–395–3952. Electronic mail comments may be submitted via Internet to TRAN__H@A1.EOP.GOV. Please include the full body of electronic mail comments in the text and not as an attachment. Please include the name, title, organization, postal address, and E-mail address in the text of the message.

FOR FURTHER INFORMATION CONTACT: Non-Federal organizations should contact the organization's cognizant Federal agency. Federal agencies should contact Gilbert Tran, Financial Standards and Reporting Branch, Office of Federal Financial Management, Office of Management and Budget, (202) 395–3993.

SUPPLEMENTARY INFORMATION: In this issue of the Federal Register, the Office of Management and Budget (OMB) issued a final revision to OMB Circular A–122, ''Cost Principles for Non-Profit Organizations,'' regarding interest allowability. The revision was made in a continuing effort to provide consistency across OMB's cost principles Circulars A–122; A–87, ''Cost Principles for State and Local Governments;'' and A–21, ''Cost Principles for Educational Institutions,'' to ensure more comparable treatment of various types of institutions when seeking support from the Federal Government, and to promote cost effective funding decisions on the part of the Federal Government and non-profit organizations. Circular A–122 consists of the Circular as originally issued in 1980 (45 FR 46022; July 8, 1980), with amendments in 1984 (49 FR 18260; April 27, 1984), in 1987 (52 FR 19788; May 27, 1987) and in this issue. See also 60 FR 36316 (July 14, 1995) regarding equipment capitalization threshold waivers.

To further the goals stated previously, OMB proposes herein to revise the definition for equipment, to make certain additional types of costs unallowable, to modify the multiple allocation base method for computing indirect cost rate(s), and to place an upper-limit on payments for administrative expenses. The following describes each of the four proposals.

First, in the equipment definition in Attachment B, section 15, OMB is proposing to raise the threshold amount to $5000 in conformance with the threshold established in Circular A–110, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations'' (58 FR 62992; November 29, 1993). This revision will decrease burdens associated with accounting for property.

Second, OMB is proposing additional unallowable items. Some proposed unallowable costs, items (1) to (10), are already unallowable under Circulars A–87 and/or A–21 (See Circular A–87 (60 FR 26484; May 17, 1995) and Circular A–21 (56 FR 50224; October 1, 1991)) and/or the Federal Acquisition Regulation (at 48 CFR Part 31). These unallowable costs include:

(1) Advertising and public relations costs.

(2) Alcoholic beverages.

(3) Organization-furnished automobiles for personal use.

(4) Defense and prosecution of criminal and civil proceedings, claims, appeals and patent infringements.

(5) Goods and services for personal uses.

(6) Housing and living expenses of an organization's officers.

(7) Insurance against defects.

(8) Memberships in any civic, community or social organization or country club.

(9) Selling or marketing of goods or services.

(10) Trustees' travel.

OMB is proposing to make changes to items (11) to (17) for consistency with amendments made by the Federal Acquisition Streamlining Act of 1994 (FASA), Public Law 103–355. Section 2151 of FASA, by amending section 306 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 256), specified certain items of costs as not allowable under Federal covered contracts. While most of the unallowable cost items listed in FASA are precisely identical or substantively the same as are currently in Circular A–122, some of the cost items differ. They are:

(11) Payments of fines and penalties resulting from violations of, or failure to comply with, foreign laws and regulations.

(12) Costs of membership in any social, dining, or country club or organization.

(13) Costs incurred in certain severance pay package (commonly known as a ''golden parachute'' payment).

(14) Costs of severance pay to foreign nationals in excess of customary or prevailing practices.

(15) Costs of severance pay to foreign nationals in the case of termination due to closing of, or the curtailment of activities at, a United States facility in that country.

(16) Costs of advertising designed to promote the organization or its products.

(17) Costs of commercial insurance that protects against the costs for correction of defects in materials or workmanship.

OMB is proposing to add items (1) through (17) to the costs in Attachment B that are unallowable under Circular A–122.

Third, OMB is proposing a revision to Attachment A under which an organization receiving more than $10 million of Federal funding will be required to compute its indirect cost rate based on a modified total direct cost basis using the ''multiple allocation method,'' and its rate should be determined separately for the two major categories: ''Facilities'' and ''Administration.'' This proposed change would provide a standard and uniform method to calculate indirect cost rate(s) for organizations receiving more than $10 million of Federal funding. This method is consistent with that required for colleges and universities with direct costs funding covered by Circular A–21 of more than $10 million. Where the Federal funding covered in this Circular of an organization does not exceed $10 million in a fiscal year, the organization will be able to use one of the three allocation methods described in Section D of Attachment A, Allocation of Indirect Costs and Determination of Indirect Costs Rates.

Fourth and finally, OMB is proposing an upper limit of 26 percent on the ''Administration'' component of the rate in Attachment A for an organization receiving more than $10 million of Federal funding. The administrative cap is consistent with the one implemented for colleges and universities on October 1, 1991, under Circular A–21 (56 FR 50224). Organizations with an administrative component rate at or less than 26 percent will continue to recover at the current negotiated rate.

The effective date for the first, second and fourth proposals will be at the start of the next accounting period beginning on or after the first issuance of the revised Circular for which the organization has not yet established a predetermined indirect cost rate. The effective date for the second proposal is as follows. For costs charged directly, the effective date for the proposed unallowable costs will be 30 days after the final issuance of the revised Circular. For costs charged indirectly, the effective date will be at the start of the next accounting period beginning on or after the final issuance of the revised Circular for which the organization has not established a predetermined indirect cost rate.

G. Edward DeSeve,

Controller.

Proposed Revisions

Revise Attachments A and B of Circular A–122, as follows.

A. Attachment A

1. Add Subsection 3 to Section C, Indirect Costs.

3. For organizations receiving more than $10 million of Federal funding covered under this Circular, the indirect costs shall be classified within two broad categories: ''Facilities'' and ''Administration.'' ''Facilities'' is defined as depreciation and use allowances, interest on debt associated with certain buildings, equipment and capital improvements, and operations and maintenance expenses. ''Administration'' is defined as general administration and general expenses such as the director's office, accounting, personnel, project administration (when it is not directly charged to projects), and all other types of expenditures not listed specifically under one of the subcategories of Facilities (including cross allocations from other pools).

2. Add Subsections f and g to Section D.1., Allocation of Indirect Costs and Determination of Indirect Cost Rates, General:

f. Where the Federal funding covered by this Circular of an organization does not exceed $10 million in a fiscal year, the organization can use one of the three allocation methods herein described as: simple, multiple or direct allocation method. The distribution base may be total direct costs (excluding capital expenditures and other distorting items, such as major subgrants or subgrants above $25,000 of each subgrant or subcontract, regardless of the period covered by the subgrant or subcontract), direct salaries and wages, or modified total direct costs (MTDC). MTDC consists of all salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to the first $25,000 of each subgrant or subcontract. Equipment, capital expenditures, charges for patient care, rental costs and the portion in excess of $25,000 shall be excluded from MTDC. Other items may only be excluded when the Federal cost cognizant agency determines that an exclusion is necessary to avoid a serious inequity in the distribution of indirect costs.

g. Where the Federal funding covered by this Circular of an organization exceeds $10 million in a fiscal year, the

organization shall use the multiple allocation method. The distribution base shall be MTDC as described in subsection f.

3. Replace Section D.2.c. with the following:

c. The distribution basis shall comply with the conditions described in Section D.1.

4. Replace Section D.3 with the following:

3. Multiple Allocation Base Method

a. General. Where an organization receives more than $10 million of Federal funding in a fiscal year covered under this Circular or where an organization's indirect costs benefit its major functions in varying degrees, such costs shall be accumulated into separate cost groupings, as described in subsection b. Each grouping shall then be allocated individually to benefitting functions by means of a base which best measures the relative benefits. The default bases by cost pool are described in subsection c.

b. Identification of indirect costs. Cost groupings shall be established so as to permit the allocation of each grouping on the basis of benefits provided to the major functions. Each grouping shall constitute a pool of expenses that are of like character in terms of functions they benefit and in terms of the allocation base which best measures the relative benefits provided to each function. The groupings are classified within the two broad categories: ''Facilities'' and ''Administration,'' as described in Section C.3. The indirect cost pools are defined as follows:

(1) Depreciation and use allowances. The expenses under this heading are the portion of the costs of the organization's buildings, capital improvements to land and buildings, and equipment which are computed in accordance with Section 11 (''Depreciation and use allowance'').

(2) Interest. Interest on debt associated with certain buildings, equipment and capital improvements are computed in accordance with Section 23 (''Interest, fund raising, and investment management costs'').

(3) Operation and maintenance expenses. The expenses under this heading are those that have been incurred for the administration, operation, maintenance, preservation, and protection of the organization's physical plant. They include expenses normally incurred for such items as: janitorial and utility services; repairs and ordinary or normal alterations of buildings, furniture and equipment; care of grounds; maintenance and operation of buildings and other plant facilities; security; earthquake and disaster preparedness; environmental safety; hazardous waste disposal; property, liability and other insurance relating to property; space and capital leasing; facility planning and management; and, central receiving. The operation and maintenance expenses category shall also include its allocable share of fringe benefit costs, depreciation and use allowance, and interest costs.

(4) General administration and general expenses. The expenses under this heading are those that have been incurred for the overall general executive and administrative offices of the organization and other expenses of a general nature which do not relate solely to any major function of the organization. This category shall also include its allocable share of fringe benefit costs, operation and maintenance expense, depreciation and use allowances, and interest costs. Examples of this category include central offices, such as the director's office, the office of finance, business services, budget and planning, personnel, safety and risk management, general counsel, and management information systems.

In developing this cost pool, special care should be exercised to ensure that costs incurred for the same purpose in like circumstances are treated consistently as either direct or indirect costs. For example, salaries of technical staff, project supplies, project publication, telephone toll charges, computer costs, travel costs, and specialized services costs shall be treated as direct costs wherever identifiable to a particular program. The salaries and wages of administrative and pooled clerical staff should normally be treated as indirect costs. Direct charging of these costs may be appropriate where a major project or activity explicitly budgets for administrative or clerical services and other individuals involved can be identified with the program or activity. Items such as office supplies, postage, local telephone costs, periodicals and memberships should normally be treated as indirect costs.

c. Allocation bases. Actual conditions shall be taken into account in selecting the base to be used in allocating the expenses in each grouping to benefitting functions. The essential consideration in selecting a method or a base is that it be the one best suited for assigning the pool of costs to cost objectives in accordance with benefits derived; a traceable cause and effect relationship; or logic and reason, where neither the cause nor the effect of the relationship is determinable. When an allocation can be made by assignment of a cost grouping directly to the function benefited, the allocation shall be made in that manner. When the expenses in a cost grouping are more general in nature, the allocation shall be made through the use of a selected base which produces results that are equitable to both the Federal Government and the organization. The distribution shall be made in accordance with the bases described herein unless it can be demonstrated that the use of a different base would result in a more equitable allocation of the costs, or that a more readily available base would not increase the costs charged to sponsored agreements. The results of special cost studies (such as an engineering utility study) shall not be used to determine and allocate the indirect costs to sponsored agreements.

(1) Depreciation and use allowance. Depreciation and use allowance expenses shall be allocated in the following manner:

(a) Depreciation and use allowances on buildings used exclusively in the conduct of a single function, and on capital improvements and equipment used in such buildings, shall be assigned to that function.

(b) Depreciation and use allowances on buildings used for more than one function, and on capital improvements and equipment used in such buildings, shall be allocated to the individual functions performed in each building on the basis of usable square feet of space, excluding common areas, such as hallways, stairwells, and restrooms.

(c) Depreciation and use allowances on buildings, capital improvements and equipment related space (e.g., individual rooms, and laboratories) used jointly by more than one function (as determined by the users of the space) shall be treated as follows. The cost of each jointly used unit of space shall be allocated to the benefitting functions on the basis of:

(i) the employee full-time equivalents (FTEs) or salaries and wages of those individual functions benefitting from the use of that space; or

(ii) organization-wide employee FTEs or salaries and wages applicable to the benefitting functions of the organization.

(d) Depreciation or use allowances on certain capital improvements to land, such as paved parking areas, fences, sidewalks, and the like, not included in the cost of buildings, shall be allocated to user categories of employees on a FTE basis and distributed to major functions in proportion to the salaries and wages of all employees applicable to the functions.

(2) Interest. Interest costs shall be allocated in the same manner as the

depreciation or use allowance on the buildings, equipment and capital equipments to which the interest relates.

(3) Operations and maintenance expenses. Operations and maintenance expenses shall be allocated in the same manner as the depreciation and use allowance.

(4) General administration and general expenses. General administration and general expenses shall be allocated to benefitting functions based on MTDC, as described in Section D.1.f. The expenses included in this category could be grouped first according to major functions of the organization to which they render services or provide benefits. The aggregate expenses of each group shall then be allocated to benefitting functions based on MTDC.

d. Order of distribution.

(1) Indirect cost categories consisting of depreciation and use allowance, interest, operation and maintenance, and general administration and general expenses shall be allocated in that order to the remaining indirect cost categories as well as to the major functions of the organization. Other cost categories could be allocated in the order determined to be most appropriate by the organization. When cross allocation of costs is made as provided in subsection (2), this order of allocation does not apply.

(2) Normally, an indirect cost category will be considered closed once it has been allocated to other cost objectives, and costs shall not be subsequently allocated to it. However, a cross allocation of costs between two or more indirect costs categories could be used if such allocation will result in a more equitable allocation of costs. If a cross allocation is used, an appropriate modification to the composition of the indirect cost categories is required.

e. Application of indirect cost rate or rates. Except where a special indirect cost rate(s) is required in accordance with Section D.5, the separate groupings of indirect costs allocated to each major function shall be aggregated and treated as a common pool for that function. The costs in the common pool shall then be distributed to individual awards included in that function by use of a single indirect cost rate.

f. Distribution basis. Indirect costs shall be distributed to applicable sponsored agreements and other benefitting activities within each major function on the basis of MTDC, as described in Section D.1.f. An indirect cost rate shall be determined for each separate indirect cost pool developed. The rate in each case shall be stated as the percentage which the amount of the particular indirect cost pool is of the distribution base identified with that pool. Each indirect cost rate negotiation or determination shall include development of the rate for each indirect cost pool as well as the overall indirect cost rate. The indirect cost pools shall be classified within two broad categories: ''Facilities'' and ''Administration,'' as described in Section C.3.

g. Limitation on reimbursement of administrative costs.

(1) The administrative costs charged to sponsored agreements awarded or amended (including continuation and renewal awards) with effective dates beginning on or after the start of the organization's first fiscal year which begins on or after October 1, 1995, shall be limited to 26 percent of MTDC (as defined in Section D.1.f) for the administration costs (including their allocable share of depreciation and/or use allowance, interest costs, operation and maintenance, and fringe benefits) and all other types of expenditures not listed specifically under one of the subcategories of facilities in Section C.3.

(2) For organizations that already established predetermined rates beyond October 1, 1995, the limitation shall be at the start of the next fiscal year beginning on or after October 1, 1995, for which the organization has not yet established an indirect cost rate.

(3) Organizations shall not change their accounting or cost allocations methods which were in effect on September 30, 1995, if the effect is to change the charging of a particular cost from indirect to direct to avoid the limitation on administrative costs. Cognizant Federal agencies are authorized to permit changes where an organization's charging practices are at variance with acceptable practices followed by a substantial majority of other similar organizations.

B. Attachment B

Revise the following cost items in Attachment B to Circular A–122 (''Selected Items of Cost'').

1. Revise the Table of Contents for Attachment B to read:

1. Advertising and public relations costs
2. Alcoholic beverages
3. Bad debts
4. Bid and proposal costs (reserved)
5. Bonding costs
6. Communication costs
7. Compensation for personal services
8. Contingency provisions
9. Contributions
10. Defense and prosecution of criminal and civil proceedings, claims, appeals and patent infringement
11. Depreciation and use allowances
12. Donations
13. Employee morale, health and welfare costs and credits
14. Entertainment costs
15. Equipment and other capital expenditures
16. Fines and penalties
17. Fringe benefits
18. Goods or services for personal use
19. Housing and personal living expenses
20. Idle facilities and idle capacity
21. Independent research and development (reserved)
22. Insurance and indemnification
23. Interest, fund raising, and investment management costs
24. Labor relations costs
25. Lobbying costs
26. Losses on other awards
27. Maintenance and repair costs
28. Materials and supplies
29. Meetings and conferences
30. Memberships, subscriptions, and professional activity costs
31. Organization costs
32. Overtime, extra-pay shift, and multi-shift premiums
33. Page charges in professional journals
34. Participant support costs
35. Patent costs
36. Pension plans
37. Plant security costs
38. Pre-award costs
39. Professional service costs
40. Profits and losses on disposition of depreciable property or other capital assets
41. Public information service costs
42. Publication and printing costs
43. Rearrangement and alteration costs
44. Reconversion costs
45. Recruiting costs
46. Relocation costs
47. Rental costs
48. Royalties and other costs for use of patents and copyrights
49. Selling and marketing
50. Severance pay
51. Specialized service facilities
52. Taxes
53. Termination costs
54. Training and education costs
55. Transportation costs
56. Travel costs
57. Trustees

2. Revise and retitle Section 1 to read:

1. Advertising and public relations costs.

a. The term advertising costs means the costs of advertising media and corollary administrative costs. Advertising media include magazines, newspapers, radio and television programs, direct mail, exhibits, and the like.

b. The term public relations includes community relations and means those activities dedicated to maintaining the image of the organization or maintaining or promoting understanding and favorable relations with the community or public at large or any segment of the public.

c. The only allowable advertising costs are those which are solely for:

(1) The recruitment of personnel required for the performance by the organization of obligations arising under a sponsored agreement, when considered in conjunction with all other recruitment costs, as set forth in Section 45 (''Recruiting costs'');

(2) The procurement of goods and services for the performance of a sponsored agreement;

(3) The disposal of scrap or surplus materials acquired in the performance of a sponsored agreement except when organizations are reimbursed for disposal costs at a predetermined amount in accordance with OMB Circular A–110, paragraph _____. 34, ''Equipment''; or

(4) Other specific purposes necessary to meet the requirements of the sponsored agreement.

d. The only allowable public relations costs are:

(1) Costs specifically required by sponsored agreements;

(2) Costs of communicating with the public and press pertaining to specific activities or accomplishments which result from performance of sponsored agreements; or

(3) Costs of conducting general liaison with news media and government public relations officers, to the extent that such activities are limited to communication and liaison necessary to keep the public informed on matters of public concern, such as notices of contract/grant awards, financial matters, etc.

e. Costs identified in subsections c. and d. if incurred for more than one sponsored agreement or for both sponsored work and other work of the organization, are allowable to the extent that the principles in Sections B (''Direct Costs'') and C (''Indirect Costs'') are observed.

f. Unallowable advertising and public relations costs include the following:

(1) All advertising and public relations costs other than as specified in subsections c., d., and e.;

(2) Costs of meeting or other events related to fund raising or other organizational activities including:

(i) Costs of displays, demonstrations, and exhibits;

(ii) Costs of meeting rooms, hospitality suites, and other special facilities used in conjunction with shows and other special events; and

(iii) Salaries and wages of employees or cost of services engaged in setting up and displaying exhibits, making demonstrations, and providing briefings;

(3) Costs of promotional items and memorabilia, including models, gifts, and souvenirs;

(4) Costs of advertising and public relations designed solely to promote the organization.

3. Renumber current sections 2 through 8 as sections 3 through 9, respectively.

4. Add the following new section 2:

2. Alcoholic beverages. Costs of alcoholic beverages are unallowable.

5. In section 7 (''Compensation for personal services''), as renumbered above in item 3, rename the current subsection g, Pension costs, as subsection h. Add a new subsection g:

g. Organization-furnished automobiles. That portion of the cost of organization-furnished automobiles that relates to personal use by employees (including transportation to and from work) is unallowable regardless of whether the cost is reported as taxable income to the employees.

6. Renumber current sections 9 through 15 as sections 11 through 17, respectively.

7. Add new section 10:

10. Defense and prosecution of criminal and civil proceedings, claims, appeals and patent infringement.

a. Definitions.

(1) Conviction, as used herein, means a judgment or a conviction of a criminal offense by any court of competent jurisdiction, whether entered upon as a verdict or a plea, including a conviction due to a plea of *nolo contendere.*

(2) Costs include, but are not limited to: administrative and clerical expenses; the cost of legal services, whether performed by in-house or private counsel; and the costs of the services of accountants, consultants, or others retained by the organization to assist it; costs of employees, officers and trustees, and any similar costs incurred before, during, and after commencement of a judicial or administrative proceeding that bears a direct relationship to the proceedings.

(3) Fraud, as used herein, means (i) acts of fraud corruption or attempts to defraud the Federal Government or to corrupt its agents, (ii) acts that constitute a cause for debarment or suspension (as specified in agency regulations), and (iii) acts which violate the False Claims Act, 31 U.S.C., sections 3729–3731, or the Anti-Kickback Act, 41 U.S.C., sections 51 and 54.

(4) Penalty does not include restitution, reimbursement, or compensatory damages.

(5) Proceeding includes an investigation.

b. (1) Except as otherwise described herein, costs incurred in connection with any criminal, civil or administrative proceeding (including filing of a false certification) commenced by the Federal Government, or a State, local or foreign government, are not allowable if the proceeding: (1) relates to a violation of, or failure to comply with, a Federal, State, local or foreign statute or regulation by the organization (including its agents and employees), and (2) results in any of the following dispositions:

(a) In a criminal proceeding, a conviction.

(b) In a civil or administrative proceeding involving an allegation of fraud or similar misconduct, a determination of organizational liability.

(c) In the case of any civil or administrative proceeding, the imposition of a monetary penalty.

(d) A final decision by an appropriate Federal official to debar or suspend the organization, to rescind or void an award, or to terminate an award for default by reason of a violation or failure to comply with a law or regulation.

(e) A disposition by consent or compromise, if the action could have resulted in any of the dispositions described in (a), (b), (c) or (d).

(2) If more than one proceeding involves the same alleged misconduct, the costs of all such proceedings shall be unallowable if any one of them results in one of the dispositions shown in subsection b.(1).

c. If a proceeding referred to in subsection b. is commenced by the Federal Government and is resolved by consent or compromise pursuant to an agreement entered into by the organization and the Federal Government, then the costs incurred by the organization in connection with such proceedings that are otherwise not allowable under subsection b. may be allowed to the extent specifically provided in such agreement.

d. If a proceeding referred to in subsection b. is commenced by a State, local or foreign government, the authorized Federal official may allow the costs incurred by the organization for such proceedings, if such authorized official determines that the costs were incurred as a result of (1) a specific term or condition of a federally-sponsored agreement, or (2) specific written direction of an authorized official of the sponsoring agency.

e. Costs incurred in connection with proceedings described in subsection b., but which are not made unallowable by that subsection, may be allowed by the Federal Government, but only to the extent that:

(1) The costs are reasonable in relation to the activities required to deal with the proceeding and the underlying cause of action;

(2) Payment of the costs incurred, as allowable and allocable costs, is not prohibited by any other provision(s) of the sponsored agreement;

(3) The costs are not otherwise recovered from the Federal Government or a third party, either directly as a result of the proceeding or otherwise; and,

(4) The percentage of costs allowed does not exceed the percentage determined by an authorized Federal official to be appropriate, considering the complexity of procurement litigation, generally accepted principles governing the award of legal fees in civil actions involving the United States as a party, and such other factors as may be appropriate. Such percentage shall not exceed 80 percent. However, if an agreement reached under subsection c. has explicitly considered this 80 percent limitation and permitted a higher percentage, then the full amount of costs resulting from that agreement shall be allowable.

f. Costs incurred by the organization in connection with the defense of suits brought by its employees or ex-employees under section 2 of the Major Fraud Act of 1988 (Pub. L. 100–700), including the cost of all relief necessary to make such employee whole, where the organization was found liable or settled, are unallowable.

g. Costs of legal, accounting, and consultant services, and related costs, incurred in connection with defense against Federal Government claims or appeals, or the prosecution of claims or appeals against the Federal Government, are unallowable.

h. Costs of legal, accounting, and consultant services, and related costs, incurred in connection with patent infringement litigation, are unallowable unless otherwise provided for in the sponsored agreements.

i. Costs which may be unallowable under this section, including directly associated costs, shall be segregated and accounted for by the organization separately. During the pendency of any proceeding covered by subsections b. and f. of this section, the Federal Government shall generally withhold payment of such costs. However, if in the best interests of the Federal Government, the Federal Government may provide for conditional payment upon provision of adequate security, or other adequate assurance, and agreements by the organization to repay all unallowable costs, plus interest, if the costs are subsequently determined to be unallowable.

8. In section 15 (''Equipment and other capital expenditures''), as renumbered in item 6 above, replace subsection 15.a.(1):

(1) ''Equipment'' means an article of nonexpendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals or exceeds the lesser of (a) the capitalization level established by the organization for the financial statement purposes, or (b) $5000.

9. Renumber current sections 16 through 44 as sections 20 through 48, respectively.

10. Add new section 18:

18. Goods or services for personal use. Costs of goods or services for personal use of the organization's employees are unallowable regardless of whether the cost is reported as taxable income to the employees.

11. Add new section 19:

19. Housing and personal living expenses.

a. Costs of housing (e.g., depreciation, maintenance, utilities, furnishings, rent, etc.), housing allowances and personal living expenses for/of the organization's officers are unallowable regardless of whether the cost is reported as taxable income to the employees.

b. The term ''officers'' includes current and past officers.

12. Add to renumbered section 22 (''Insurance and indemnification'') subsections (f) and (g) to section 22.a.(2):

(f) Insurance against defects. Costs of insurance with respect to any costs incurred to correct defects in the organization's materials or workmanship are unallowable.

(g) Medical liability (malpractice) insurance is an allowable cost of research programs only to the extent that the research involves human subjects. Medical liability insurance costs shall be treated as a direct cost and shall be assigned to individual projects based on the manner in which the insurer allocates the risk to the population covered by the insurance.

13. Revise section 30, as renumbered in item 9, to read:

30. Memberships, subscriptions and professional activity costs.

a. Costs of the organization's membership in business, technical, and professional organizations are allowable.

b. Costs of the organization's subscriptions to business, professional, and technical periodicals are allowable.

c. Costs of meetings and conferences, when the primary purpose is the dissemination of technical information, are allowable. This includes costs of meals, transportation, rental of facilities, and other items incidental to such meetings or conferences.

d. Costs of membership in any civic or community organization are unallowable.

e. Costs of membership in any country club or social or dining club or organization are unallowable.

14. Revise section 45, as renumbered in item 9, to read:

45. Recruiting costs.

a. Subject to subsections b., c., and d., and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of ''help wanted'' advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation costs incurred incident to recruitment of new employees, are allowable to the extent that such costs are incurred pursuant to a well managed recruitment program. Where the organization uses employment agencies, costs that are not in excess of standard commercial rates for such services are allowable.

b. In publications, costs of help wanted advertising that includes color, includes advertising material for other than recruitment purposes, or is excessive in size (taking into consideration recruitment purposes for which intended and normal organizational practices in this respect), are unallowable.

c. Costs of help wanted advertising, special emoluments, fringe benefits, and salary allowances incurred to attract professional personnel from other organizations that do not meet the test of reasonableness or do not conform with the established practices of the organization, are unallowable.

d. Where relocation costs incurred incident to recruitment of a new employee have been allowed either as an allocable direct or indirect cost, and the newly hired employee resigns for reasons within his control within twelve months after being hired, the organization will be required to refund or credit such relocation costs to the Federal Government.

15. Current sections 45 through 51 are renumbered as sections 50 through 56, respectively.

16. Add new section 49:

49. Selling and marketing. Costs of selling and marketing any products or services of the organization (unless

allowed under section 1) are unallowable.

17. In section 50 (''Severance pay''), as renumbered in item 15, subsection a. is amended and new subsections c. and d. are added, as follows:

a. Severance pay, also commonly referred to as dismissal wages, is a payment in addition to regular salaries and wages, by organizations to workers whose employment is being terminated. Costs of severance pay are allowable only to the extent that in each case, they are required by: (i) law; (ii) employer-employee agreement in effect at time of establishment of the contract or grant, or at commencement of employment; (iii) preexisting established policy that constitutes, in effect, an implied agreement on the organization's part; or (iv) circumstances of the particular employment.

Costs incurred in certain severance pay packages (commonly known as ''a golden parachute'' payment) which are in an amount in excess of the normal severance pay paid by the organization to an employee upon termination of employment and are paid to the employee contingent upon a change in management control over, or ownership of, the organization's assets are unallowable.

c. Severance payments to foreign nationals employed by the organization outside the United States, to the extent that the amount exceeds the customary or prevailing practices for the organization in the United States are unallowable.

d. Severance payments to foreign nationals employed by the organization outside the United States due to the termination of the foreign national as a result of the closing of, or curtailment of activities by, the organization in that country, are unallowable.

18. Add new section 57:

57. Trustees. Travel and subsistence costs of trustees, regardless of the purpose of the trip, are unallowable.

[FR Doc. 95–24900 Filed 10–5–95; 8:45 am]

BILLING CODE 3110–01–P

federal register

Friday
October 6, 1995

Part V

Department of Health and Human Services

Health Care Financing Administration

Public Information Collection Requirements Submitted to OMB for Clearance; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB) for Clearance

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (HHS), has submitted to OMB the following information collection requirement for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320, in order to analyze and pay claims submitted by certain medical suppliers, and is essential to the mission of HCFA. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result if normal clearance procedures are followed. Without this information, HCFA could not authorize payment for only those services that are reasonable and necessary (Sections 1834 and 1861 of the Social Security Act).

HCFA is requesting that OMB provide a two-day review and a 90-day approval. During this 90-day period HCFA will publish a separate Federal Register notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. Then HCFA will submit the requirements for OMB review and an extension of this emergency approval.

1. *Type of Information Collection Request:* Emergency; *Title of Information Collection:* Durable Medical Equipment Regional Carrier, Certificate of Medical Necessity, Version I and Version II. (Either version may be used through April 1, 1996); *Form No.:* HCFA–R–182; *Use:* This information is needed to correctly process claims and insure that claims are properly paid. These forms contain medical information necessary to make an appropriate determination.

Frequency: On occasion; *Affected Public:* Suppliers and Physicians, Business or other for-profit, Federal Government; *Number of Respondents:* 140,000; *Total Annual Responses:* 6.8 million; *Total Annual Hours Requested:* 1.7 million.

To request copies of the proposed paperwork collection referenced above, call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 2 working days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 3, 1995.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff.

BILLING CODE 4120–03–P

Effective 10/93 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 10.01

CERTIFICATE OF MEDICAL NECESSITY: PARENTERAL OR ENTERAL NUTRITION

SECTION A ☐ **INITIAL** ☐ **REVISED** ☐ **RECERTIFICATION**

PATIENT NAME, ADDRESS, TELEPHONE AND HIC NO.

(_ _ _) _ _ _ - _ _ _ _ HICN_____

SUPPLIER NAME, ADDRESS, TELEPHONE, AND NSC NUMBER

(_ _ _) _ _ _ - _ _ _ _ NSC _____

PLACE OF SERVICE ____ REPLACEMENT ITEM ____

NAME AND ADDRESS OF FACILITY IF APPLICABLE (SEE BACK OF FORM):

HCPCS CODE(S)	WARRANTY	LENGTH	TYPE

SECTION B **CLINICAL INFORMATION**

DIAGNOSIS (ICD9): ____ ____ ____ ____

PT. HT. ____ (IN.) PT. WT. ____ (LBS) DOB ____/____/____

I LAST EXAMINED THIS PATIENT FOR THIS CONDITION ON: ____/____/____ PT. SEX ____ (M OR F)

DATE NEEDED INIT ____/____/____ REV/RECERT ____/____/____
EST. LENGTH OF NEED: # OF MONTHS: ___ 1-99 (99 = LIFETIME)

ANSWER QUESTIONS 1-6 FOR PARENTERAL, ANSWER 2, 6-15 FOR ENTERAL Use Y - Yes, N - No or D for Does Not Apply unless otherwise noted.

[ ] 1. Does the patient have severe permanent disease of the gastrointestinal tract which prevents absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status?

[ ] 2. Do the number of calories prescribed average 20-35 cal/kg/day?

[ ] 3. Days per week infused? Enter 1-7.

4. Formula components:

Amino acid _____(ml/day) _____ concen % _____ gms protein/day

Dextrose_____ (ml/day) _____ concen %

Lipids _____ ml/day _____ days/week _____ concen %

[ ] 5. What is the route of administration?
1 - Central line
2 - Peripheral line
3 - Hemodialysis access line
7 - Peripherally inserted central catheter (PICC)

[ ] 6. Has there been a break in therapy of two or more consecutive months, necessitating a new certification, during which time the patient did not receive enteral or parenteral feeding?

[ ] 7. Does the patient have permanent nonfunction or disease of the structures that normally permit food to reach the small bowel?

[ ] 8. Does the patient require tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status?

[ ] 9. What is the prescribed route of administration?
4 - Nasogastric tube
5 - Gastrostomy tube
6 - Jejunostomy tube

10. Product name? _____

11. Calories per day? _____

[ ] 12. Days per week administered? Enter 1-7.

[ ] 13. Method of administration?
1 - Syringe
2 - Gravity
3 - Pump

[ ] 14. Does the patient have a documented allergy or intolerance to semi-synthetic nutrients?

15. Additional information when required by policy:

_____

_____

_____

I certify the medical necessity of these items for this patient. Section B of this form and any statement on my letterhead attached hereto has been completed by me or reviewed by me. The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN NAME, ADDRESS

_____ ___/___/___
PHYSICIAN'S SIGNATURE DATE
(A STAMPED SIGNATURE IS NOT ACCEPTABLE)

☐ Attending ☐ Consulting ☐ Other ordering

UPIN:_____

TELEPHONE #: (_ _ _) _ _ _ - _ _ _ _

DME 6/93

SECTION A: (To be completed by the supplier)

CERTIFICATION TYPE:	Check the appropriate box to indicate if this CMN is the initial certification, revised certification, or recertification. Refer to your supplier manual for more information.
BENEFICIARY INFORMATION:	Indicate the beneficiary's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the beneficiary's Medicare card and on your claim form.
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to your supplier manual for a complete index.
REPLACEMENT:	If the item billed is a replacement for a previously purchased item, place a check mark in the blank.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
HCPCS CODES:	List all procedure codes for items ordered that require a CMN. Procedure codes that do not require a certification should not be listed on the CMN. If the item ordered is purchased equipment, indicate whether the equipment is covered by a warranty. "Y" denotes that there is a warranty and "N" indicates there is no warranty. If it is covered by a warranty, the length and type of warranty must be indicated.

SECTION B: (To be completed or reviewed and signed by the ordering physician)

DIAGNOSIS:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3).
EXAMINATION DATE:	Indicate the date (MM/DD/YY) the patient was last seen by the ordering physician prior to the beginning of this certification period.
PT. HT., PT. WT., DOB:	Indicate the patient's height in inches and weight in pounds. Indicate patient's date of birth (MM/DD/YY).
DATE NEEDED:	Indicate the date (MM/DD/YY) the ordered item was initially needed outside the hospital setting. If this certification is a revised certification, also indicate the effective date of the order change.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question within the category for the items ordered, using "Y" for yes, "N" for no, and "D" for does not apply, unless otherwise noted.
PHYSICIAN INFORMATION:	The physician's signature certifies that the item ordered is medically necessary for this patient and that section B was completed or reviewed by the physician. This form must be signed and dated by the physician. Signature and date stamps are not acceptable. The physician must indicate whether he/she is the attending, consulting or other ordering physician by putting a check mark in the appropriate box. Indicate other ordering when you are neither the attending or consulting physician. Refer to your supplier manual for more information.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	The physician must indicate his/her Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	The physician must give a telephone number where he/she can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Department of Health and Human Services
Health Care Financing Administration

Form Approved
OMB No. 0938-0534

ATTENDING PHYSICIAN'S CERTIFICATION OF MEDICAL NECESSITY FOR HOME OXYGEN THERAPY *(Legible handwritten entries acceptable)*

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HCFA, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Patient's Name, Address, and HIC No.	Supplier's Name, Address, and Identification No.

Certification: ☐ Initial ☐ Revised ☐ Renewed

INFORMATION BELOW TO BE ENTERED ONLY BY PHYSICIAN OR PHYSICIAN'S EMPLOYEE

1. Pertinent Diagnoses, ICD-9-CM Codes, and Findings - CHECK ALL THAT APPLY:

☐ Emphysema (492.8)
☐ COPD (496)
☐ Cor Pulmonale (416.9)
☐ Interstitial Disease (515)
☐ Other _____ Specify Code
☐ Chronic Obstructive Bronchitis (491.2)
☐ Chronic Obstructive Asthma (493.20)
☐ Congestive Heart Failure (428.0)
☐ Secondary Polycythemia (289.0)
☐ Hematocrit 57% or more Yes ☐ No ☐

2.A. I last examined this patient for this condition on: _____/_____/_____ Month Day Year

2.B. Home oxygen prescribed: _____/_____/_____ Month Day Year

2.C. Estimated length of need: ☐ 1-3 months ☐ 4-12 months ☐ Lifetime

3.A. Results of Most Recent Arterial Blood Gas and/or Oxygen Saturation Tests (Patient Breathing Room Air)

	PO2	02 Saturation	Date
(1) At Rest			
(2) Walking			
(2) Sleeping			
(3) Exercising			
(4) Other :			

3.C. Physician/Provider Performing Test(s) *(Printed/Typed Name and Address)*:

3.B. If performed under conditions other than room air, explain:

NOTE: If PO2 Level exceeds 59 mm Hg or the arterial blood saturation exceeds 89% at rest on room air, the claim will be disallowed without compelling medical evidence. Check block ☐ if you have attached a separate statement on your letterhead of additional documentation.

4. Oxygen Flow Rate : _____ Liters per minute ☐ Continuous (24 hrs/day)

☐ Noncontinuous (Enter hrs/day): _____ Walking _____ Sleeping _____ Exercise Program _____ Other (specify) _____

5. Oxygen Equipment Prescribed If you have prescribed a particular form of delivery, check applicable block(s). Otherwise leave blank.

A. Supply System

(1) Stationary Source ☐ Concentrator ☐ Liquid Oxygen ☐ Compressed Gas ☐ Other

(2) Portable or Ambulatory Source ☐ Liquid Oxygen ☐ Compressed Gas ☐ Other _____

B. Delivery System

☐ (1) Nasal Cannula
☐ (2) 02 Conserving Device
☐ Pulse 02 System
☐ Reservoir System
☐ Other _____
☐ (3) Transtracheal Catheter
☐ (4) Other _____

6. If you have prescribed a portable or ambulatory system, describe activities/exercise that patient regularly pursues which require this system in the home and which cannot be met by a stationary system (e.g., amount and frequency of ambulation).

CERTIFICATION

THE PATIENT HAS APPROPRIATELY TRIED OTHER TREATMENT MEASURES WITHOUT SUCCESS. OXYGEN THERAPY AND OXYGEN EQUIPMENT AS PRESCRIBED IS MEDICALLY INDICATED AND IS REASONABLE AND NECESSARY FOR THE TREATMENT OF THIS PATIENT. THIS FORM AND ANY STATEMENT ON MY LETTERHEAD ATTACHED HERETO HAS BEEN COMPLETED BY ME, OR BY MY EMPLOYEE AND REVIEWED BY ME. THE FOREGOING INFORMATION IS TRUE, ACCURATE, AND COMPLETE, AND I UNDERSTAND THAT ANY FALSIFICATION, OMISSION, OR CONCEALMENT OF MATERIAL FACT MAY SUBJECT ME TO CIVIL OR CRIMINAL LIABILITY.

Attending Physician's Signature: *(A STAMPED SIGNATURE IS NOT ACCEPTABLE)*	Date:

Physician's Name, Address, Telephone No., and Identification No.:

Form HCFA-484 (5-90)

• U.S. GPO 1995

Effective 10/93 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 09.01

CERTIFICATE OF MEDICAL NECESSITY: INFUSION PUMPS/HOME GLUCOSE MONITORS

SECTION A **CERTIFICATION:** ☐ **INITIAL** ☐ **REVISED**

PATIENT NAME, ADDRESS, TELEPHONE AND HIC NO.

(___) ___-____ HICN_____

SUPPLIER NAME, ADDRESS, TELEPHONE, AND NSC NUMBER

(___) ___-____ NSC _____

PLACE OF SERVICE ____ REPLACEMENT ITEM ____

NAME AND ADDRESS OF FACILITY IF APPLICABLE (SEE BACK OF FORM):

HCPCS CODE(S)	WARRANTY	LENGTH	TYPE
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

SECTION B **INFORMATION BELOW TO BE COMPLETED ONLY BY THE PHYSICIAN OR PHYSICIAN'S EMPLOYEE**

DIAGNOSIS (ICD9): _____ _____ _____ _____

PT. HT. ____ (IN.) PT. WT. ____ (LBS) DOB ____/____/____

I LAST EXAMINED THIS PATIENT FOR THIS CONDITION ON: _____/_____/_____ PT. SEX ____ (M OR F)

DATE NEEDED INITIAL ____/____/____ REVISED ____/____/____
EST. LENGTH OF NEED: # OF MONTHS: ____ 1-99 (99 = LIFETIME)

ANSWER QUESTIONS 1-6 FOR INFUSION PUMPS, ANSWER 9-13 FOR HOME GLUCOSE MONITORS Use Y - Yes, N - No or D for Does Not Apply unless otherwise noted.

INFUSION PUMP

____ 1. Which pump has been prescribed?
- 1 - Ambulatory infusion pump
- 2 - Stationary infusion pump
- 3 - Implantable infusion pump
- 4 - Disposable infusion pump (e.g., elastomeric)

2. Provide the HCPCS code for the drug that requires the use of the pump.

_____

3. If a non-specific code was used to answer question 2, provide the name of the drug.

_____

____ 4. What is the route of administration?
- 1 - Intravenous
- 2 - Intra-arterial
- 3 - Epidural
- 4 - Subcutaneous

____ 5. What is the method of administration?
- 1 - Continuous
- 2 - Intermittent
- 3 - Bolus

____ 6. What is the total duration of drug infusion per 24 hours? (Enter number of hours 1 - 24).

[ ] 7. Does the patient have intractable cancer pain which has failed to respond to an adequate oral/transdermal narcotic analgesic regimen or is the patient unable to tolerate oral/transdermal narcotics?

[ ] 8. Is the patient a cardiac transplant candidate on active status?

HOME GLUCOSE MONITOR

[ ] 9. Does the patient have insulin-treated diabetes?

[ ] 10. Does the patient have documented episodes of
- widely fluctuating blood sugars, and/or
- recurring insulin reactions, and/or
- ketoacidosis?

[ ] 11. Is the patient or caregiver capable of learning proper operation of the device?

[ ] 12. Is the device designed for home rather than clinic use?

____ 13. Approximately how many times per week is the patient expected to check his/her blood sugar? Enter the number of times per week 01 - 99.

I certify the medical necessity of these items for this patient. Section B of this form and any statement on my letterhead attached hereto has been completed by me, or by my employee and reviewed by me. The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN NAME, ADDRESS

_____ __/__/__
PHYSICIAN'S SIGNATURE: DATE
(A STAMPED SIGNATURE IS NOT ACCEPTABLE)

☐ Attending ☐ Consulting ☐ Other ordering

UPIN:_____

TELEPHONE #: (___) ___-____

08/16/93

SECTION A: (To be completed by the supplier)

CERTIFICATION TYPE:	Check the appropriate box to indicate if this CMN is the initial certification for this patient or if this is a revised certification.
BENEFICIARY INFORMATION:	Indicate the beneficiary's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the beneficiary's Medicare card and on your claim form.
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to your supplier manual for a complete index.
REPLACEMENT:	If the item billed is a replacement for a previously purchased item, place a check mark in the blank.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
HCPCS CODES:	List all procedure codes for items ordered that require a CMN. Procedure codes that do not require a certification should not be listed on the CMN. If the item ordered is purchased equipment, indicate whether the equipment is covered by a warranty. "Y" denotes that there is a warranty and "N" indicates there is no warranty. If it is covered by a warranty, the length and type of warranty must be indicated.

SECTION B: (To be completed by the physician or physician's employee)

DIAGNOSIS:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3).
EXAMINATION DATE:	Indicate the date (MM/DD/YY) the patient was last seen by the ordering physician prior to the beginning of this certification period.
PT. HT., PT. WT., DOB:	Indicate the patient's height in inches and weight in pounds (for infusion pumps). Indicate patient's date of birth (MM/DD/YY).
DATE NEEDED:	Indicate the date (MM/DD/YY) the ordered item was initially needed outside the hospital setting. If this certification is a revised certification, also indicate the effective date of the order change.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question within the category of the items ordered, using "Y" for yes, "N" for no, and "D" for does not apply, unless otherwise noted.
PHYSICIAN INFORMATION:	The physician's signature certifies that the item ordered is medically necessary for this patient and that section B was completed or reviewed by the physician. This form must be signed and dated by the physician. Signature and date stamps are not acceptable. The physician must indicate whether he/she is the attending, consulting or other ordering physician by putting a check mark in the appropriate box. Indicate other ordering when you are neither the attending or consulting physician. Refer to your supplier manual for more information.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	The physician must indicate his/her Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	The physician must give a telephone number where he/she can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/93 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 08.01

CERTIFICATE OF MEDICAL NECESSITY IMMUNOSUPPRESSIVE DRUGS

SECTION A **CERTIFICATION:** ☐ **INITIAL** ☐ **REVISED**

PATIENT NAME, ADDRESS, TELEPHONE AND HIC NO.

(___) ___ - ____ HICN_____

SUPPLIER NAME, ADDRESS, TELEPHONE, AND NSC NUMBER

(___) ___ - ____ NSC _____

PLACE OF SERVICE ____ REPLACEMENT ITEM ____

NAME AND ADDRESS OF FACILITY IF APPLICABLE (SEE BACK OF FORM):

HCPCS CODE(S)	WARRANTY	LENGTH	TYPE

SECTION B **CLINICAL INFORMATION**

DIAGNOSIS (ICD9): ____ ____ ____ ____

PT. HT. ____ (IN.) PT. WT. ____ (LBS) DOB ____/____/____

I LAST EXAMINED THIS PATIENT FOR THIS CONDITION ON: ____/____/____ PT. SEX ____ (M OR F)

DATE NEEDED INITIAL ____/____/____ REVISED ____/____/____
EST. LENGTH OF NEED: # OF MONTHS: ____ 1-99 (99 = LIFETIME)

ANSWER QUESTIONS 1-12 FOR IMMUNOSUPPRESSIVE DRUGS Use Y - Yes, N - No or D for Does Not Apply unless otherwise noted.

What are the drug(s) prescribed and the dosage and frequency of administration of each?

	HCPCS	MG	TIMES PER DAY
1.	____	____	____
2.	____	____	____
3.	____	____	____

[ ] 4. Has the patient had an organ transplant that was covered by Medicare?

___ 5. Which organ/organs have been transplanted? (Most recent transplant)
___
___
1 - Heart
2 - Liver
3 - Kidney
4 - Bone Marrow
5 - Lung
May enter up to three different organs.

6. On what date was the transplant surgery performed, requiring this therapy?

____/____/____

7. Transplant procedure code (CPT code).

_____

8. Name of facility where transplant was performed.

_____

9. City where facility is located.

_____

___ 10. State where facility is located.

11. On what date was the patient discharged from the hospital following this transplant surgery?

____/____/____

[ ] 12. Was there a prior transplant failure of this same organ?

I certify the medical necessity of these items for this patient. Section B of this form and any statement on my letterhead attached hereto has been completed by me, or reviewed by me. The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN NAME, ADDRESS

PHYSICIAN'S SIGNATURE: _____ __/__/__ DATE
(A STAMPED SIGNATURE IS NOT ACCEPTABLE)

☐ Attending ☐ Consulting ☐ Other ordering

UPIN: _____

TELEPHONE #: (___) ___ - ____

6 93

SECTION A: (To be completed by the supplier)

CERTIFICATION TYPE:	Check the appropriate box to indicate if this CMN is the initial certification for this patient or if this is a revised certification.
BENEFICIARY INFORMATION:	Indicate the beneficiary's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the beneficiary's Medicare card and on your claim form.
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to your supplier manual for a complete index.
REPLACEMENT:	If the item billed is a replacement for a previously purchased item, place a check mark in the blank.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
HCPCS CODES:	List all procedure codes for items ordered that require a CMN. Procedure codes that do not require a certification should not be listed on the CMN. If the item ordered is purchased equipment, indicate whether the equipment is covered by a warranty. "Y" denotes that there is a warranty and "N" indicates there is no warranty. If it is covered by a warranty, the length and type of warranty must be indicated.

SECTION B: (To be completed or reviewed and signed by the ordering physician)

DIAGNOSIS:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3).
EXAMINATION DATE:	Indicate the date (MM/DD/YY) the patient was last seen by the ordering physician prior to the beginning of this certification period.
PT. HT., PT. WT., DOB:	Indicate the patient's height in inches and weight in pounds. Indicate patient's date of birth (MM/DD/YY).
DATE NEEDED:	Indicate the date (MM/DD/YY) the ordered item was initially needed outside the hospital setting. If this certification is a revised certification, also indicate the effective date of the order change.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question, using "Y" for yes, "N" for no, and "D" for does not apply, unless otherwise noted.
PHYSICIAN INFORMATION:	The physician's signature certifies that the item ordered is medically necessary for this patient and that section B was completed or reviewed by the physician. This form must be signed and dated by the physician. Signature and date stamps are not acceptable. The physician must indicate whether he/she is the attending, consulting or other ordering physician by putting a check mark in the appropriate box. Indicate other ordering when you are neither the attending or consulting physician. Refer to your supplier manual for more information.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	The physician must indicate his/her Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	The physician must give a telephone number where he/she can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/93 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 07.01

CERTIFICATE OF MEDICAL NECESSITY: SEAT LIFT MECHANISMS/POWER OPERATED VEHICLES (POV)

SECTION A **CERTIFICATION:** ☐ **INITIAL** ☐ **REVISED**

PATIENT NAME, ADDRESS, TELEPHONE AND HIC NO.

(___) ___-____ HICN_____

SUPPLIER NAME, ADDRESS, TELEPHONE, AND NSC NUMBER

(___) ___-____ NSC _____

PLACE OF SERVICE ____ REPLACEMENT ITEM ____

NAME AND ADDRESS OF FACILITY IF APPLICABLE (SEE BACK OF FORM):

HCPCS CODE(S)	WARRANTY	LENGTH	TYPE

SECTION B **INFORMATION BELOW TO BE COMPLETED ONLY BY THE PHYSICIAN OR PHYSICIAN'S EMPLOYEE**

DIAGNOSIS (ICD9): _____ _____ _____ _____

DOB ___/___/___

I LAST EXAMINED THIS PATIENT FOR THIS CONDITION ON: ___/___/___ PT. SEX. ____ (M OR F)

DATE NEEDED INITIAL ___/___/___ REVISED ___/___/___
EST. LENGTH OF NEED: # OF MONTHS: ___ 1-99 (99 = LIFETIME)

ANSWER QUESTIONS 1-5 FOR SEAT LIFT MECHANISMS, ANSWER QUESTIONS 6-14 FOR POWER OPERATED VEHICLES (POV)
Use Y - Yes, N - No or D for Does Not Apply unless otherwise noted.

SEAT LIFT MECHANISM

[ ] 1. Does the patient have severe arthritis of the hip or knee?

[ ] 2. Does the patient have a severe neuromuscular disease?

[ ] 3. Is the patient completely incapable of standing up from a regular armchair or any chair in his/her home?

[ ] 4. Once standing, does the patient have the ability to ambulate?

[ ] 5. Have all appropriate therapeutic modalities to enable the patient to transfer from a chair to a standing position (e.g., medication, physical therapy) been tried and failed? If YES, this is documented in the patient's records.

POWER OPERATED VEHICLE

[ ] 6. Would the patient be bed or chair confined without the use of a wheelchair?

[ ] 7. Is the patient unable to operate a manual wheelchair?

[ ] 8. Can the patient ambulate in the home but the POV is required for movement outside the home?

[ ] 9. Is the patient capable of safely transferring in and out of the POV?

[ ] 10. Is the patient capable of safely operating the controls of the POV?

[ ] 11. Does the patient have adequate trunk stability to be able to safely ride in the POV?

[ ] 12. Are you a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology?

[ ] 13. Is the patient more than one day's roundtrip from a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology?

[ ] 14. Does the patient's condition preclude a visit to a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology?

I certify the medical necessity of these items for this patient. Section B of this form and any statement on my letterhead attached hereto has been completed by me, or by my employee and reviewed by me. The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN NAME, ADDRESS

PHYSICIAN'S SIGNATURE: ___/___/___ DATE
(A STAMPED SIGNATURE IS NOT ACCEPTABLE)

☐ Attending ☐ Consulting ☐ Other ordering

UPIN:_____

TELEPHONE #: (___) ___-____

08/15/93

SECTION A: (To be completed by the supplier)

CERTIFICATION TYPE:	Check the appropriate box to indicate if this CMN is the initial certification for this patient or if this is a revised certification.
BENEFICIARY INFORMATION:	Indicate the beneficiary's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the beneficiary's Medicare card and on your claim form.
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to your supplier manual for a complete index.
REPLACEMENT:	If the item billed is a replacement for a previously purchased item, place a check mark in the blank.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
HCPCS CODES:	List all procedure codes for items ordered that require a CMN. Procedure codes that do not require a certification should not be listed on the CMN. If the item ordered is purchased equipment, indicate whether the equipment is covered by a warranty. "Y" denotes that there is a warranty and "N" indicates there is no warranty. If it is covered by a warranty, the length and type of warranty must be indicated.

SECTION B: (To be completed by the physician or physician's employee)

DIAGNOSIS:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3).
EXAMINATION DATE:	Indicate the date (MM/DD/YY) the patient was last seen by the ordering physician prior to the beginning of this certification period.
DOB:	Indicate patient's date of birth (MM/DD/YY).
DATE NEEDED:	Indicate the date (MM/DD/YY) the ordered item was initially needed outside the hospital setting. If this certification is a revised certification, also indicate the effective date of the order change.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question within the category of the items ordered, using "Y" for yes, "N" for no, and "D" for does not apply, unless otherwise noted.
PHYSICIAN INFORMATION:	The physician's signature certifies that the item ordered is medically necessary for this patient and that section B was completed or reviewed by the physician. This form must be signed and dated by the physician. Signature and date stamps are not acceptable. The physician must indicate whether he/she is the attending, consulting or other ordering physician by putting a check mark in the appropriate box. Indicate other ordering when you are neither the attending or consulting physician. Refer to your supplier manual for more information.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	The physician must indicate his/her Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	The physician must give a telephone number where he/she can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/93 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 06.01**

CERTIFICATE OF MEDICAL NECESSITY: TENS

SECTION A **CERTIFICATION:** ☐ **INITIAL** ☐ **REVISED**

PATIENT NAME, ADDRESS, TELEPHONE AND HIC NO.

(_ _ _) _ _ _ - _ _ _ _ HICN_____

SUPPLIER NAME, ADDRESS, TELEPHONE, AND NSC NUMBER

(_ _ _) _ _ _ - _ _ _ _ NSC _____

PLACE OF SERVICE ____ REPLACEMENT ITEM ____

NAME AND ADDRESS OF FACILITY IF APPLICABLE (SEE BACK OF FORM):

HCPCS CODE(S)	WARRANTY	LENGTH	TYPE

SECTION B **INFORMATION BELOW TO BE COMPLETED ONLY BY THE PHYSICIAN OR PHYSICIAN'S EMPLOYEE**

DIAGNOSIS (ICD9): ____ ____ ____ ____

DOB ___/___/___

I LAST EXAMINED THIS PATIENT FOR THIS CONDITION ON: ___/___/___ PT. SEX ___ (M OR F)

DATE NEEDED INITIAL ___/___/___ REVISED ___/___/___
EST. LENGTH OF NEED: # OF MONTHS: ___ 1-99 (99 = LIFETIME)

ANSWER QUESTIONS 1-6 FOR RENTAL OF TENS, AND 3-12 FOR PURCHASE OF TENS Use Y - Yes, N - No or D for Does Not Apply unless otherwise noted.

[ ] 1. Does the patient have acute post-operative pain?

2. What is the date of the surgery resulting in acute post-operative pain?
___/___/___

[ ] 3. Does the patient have chronic, intractable pain?

___ 4. How long has the patient had intractable pain?
Enter number of months 1-99.

___ 5. For which, if any, of the following conditions is the TENS unit being prescribed?
1 - Headache
2 - Visceral abdominal pain
3 - Pelvic pain
4 - Temporomandibular joint (TMJ) pain
5 - None of the above

[ ] 6. Is there documentation in the medical record of multiple medications and/or other therapies that have been tried and failed?

[ ] 7. Has the patient received a TENS trial?

8. What are the dates that trial of TENS unit began and ended?
___/___/___ to ___/___/___

9. What is the date that you reevaluated the patient at the end of the trial period?
___/___/___

___ 10. How often has the patient been using the TENS?
1 = Daily
2 = 3 to 6 days per week
3 = 2 or less days per week

[ ] 11. Do you and the patient agree that there has been a significant improvement in the pain and that long term use of a TENS is warranted?

___ 12. Number of TENS leads (i.e., separate electrodes) routinely needed and used by the patient at any one time:
2 = 2 Leads
4 = 4 Leads

I certify the medical necessity of these items for this patient. Section B of this form and any statement on my letterhead attached hereto has been completed by me, or by my employee and reviewed by me. The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN NAME, ADDRESS

_____ __/__/__
PHYSICIAN'S SIGNATURE: DATE
(A STAMPED SIGNATURE IS NOT ACCEPTABLE)

☐ Attending ☐ Consulting ☐ Other ordering

UPIN:_____

TELEPHONE #: (_ _ _) _ _ _ - _ _ _ _

n 5 93

SECTION A: (To be completed by the supplier)

CERTIFICATION TYPE:	Check the appropriate box to indicate if this CMN is the initial certification for this patient or if this is a revised certification.
BENEFICIARY INFORMATION:	Indicate the beneficiary's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the beneficiary's Medicare card and on your claim form.
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to your supplier manual for a complete index.
REPLACEMENT:	If the item billed is a replacement for a previously purchased item, place a check mark in the blank.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
HCPCS CODES:	List all procedure codes for items ordered that require a CMN. Procedure codes that do not require a certification should not be listed on the CMN. If the item ordered is purchased equipment, indicate whether the equipment is covered by a warranty. "Y" denotes that there is a warranty and "N" indicates there is no warranty. If it is covered by a warranty, the length and type of warranty must be indicated.

SECTION B: (To be completed by the physician or physician's employee)

DIAGNOSIS:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3).
EXAMINATION DATE:	Indicate the date (MM/DD/YY) the patient was last seen by the ordering physician prior to the beginning of this certification period.
DOB:	Indicate patient's date of birth (MM/DD/YY).
DATE NEEDED:	Indicate the date (MM/DD/YY) the ordered item was initially needed outside the hospital setting. If this certification is a revised certification, also indicate the effective date of the order change.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question within the category of the items ordered, using "Y" for yes, "N" for no, and "D" for does not apply, unless otherwise noted.
PHYSICIAN INFORMATION:	The physician's signature certifies that the item ordered is medically necessary for this patient and that section B was completed or reviewed by the physician. This form must be signed and dated by the physician. Signature and date stamps are not acceptable. The physician must indicate whether he/she is the attending, consulting or other ordering physician by putting a check mark in the appropriate box. Indicate other ordering when you are neither the attending or consulting physician. Refer to your supplier manual for more information.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	The physician must indicate his/her Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	The physician must give a telephone number where he/she can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/93 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 05.01**

CERTIFICATE OF MEDICAL NECESSITY: SURGICAL DRESSINGS / UROLOGICAL SUPPLIES

SECTION A **CERTIFICATION:** ☐ **INITIAL**

PATIENT NAME, ADDRESS, TELEPHONE AND HIC NO.

(___) ___-____ HICN_____

SUPPLIER NAME, ADDRESS, TELEPHONE, AND NSC NUMBER

(___) ___-____ NSC _____

PLACE OF SERVICE ____ REPLACEMENT ITEM ____

NAME AND ADDRESS OF FACILITY IF APPLICABLE (SEE BACK OF FORM):

HCPCS CODE(S)

_____ _____ _____ _____

_____ _____ _____ _____

_____ _____ _____ _____

SECTION B **CLINICAL INFORMATION**

DIAGNOSIS (ICD9): _____ _____ _____ _____

DOB ___/___/___

I LAST EXAMINED THIS PATIENT FOR THIS CONDITION ON: ____/____/____ PT. SEX ____ (M OR F)

DATE NEEDED INITIAL ___/___/___ REVISED ___/___/___

EST. LENGTH OF NEED: # OF MONTHS: ___ 1-99 (99 = LIFETIME)

ANSWER QUESTIONS 1-3 AND 5-7 FOR SURGICAL DRESSINGS, AND 4-7 FOR UROLOGICAL SUPPLIES

Use Y - Yes, N - No or D for Does Not Apply unless otherwise noted.

SURGICAL DRESSINGS

[ ] 1. Does the patient have a surgical wound?

___ 2. Number of surgical wounds (enter number).

3. Date of surgical procedure: (MM/DD/YY) ____/____/____

UROLOGICAL SUPPLIES

[ ] 4. Does the patient have permanent urinary incontinence?

5. Dressings/Urological Supplies Ordered	6. HCPCS Code	7. Frequency of Change

I certify the medical necessity of these items for this patient. Section B of this form and any statement on my letterhead attached hereto has been completed by me or reviewed by me. The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN NAME, ADDRESS

_____ _____ ___/___/___

PHYSICIAN'S SIGNATURE: DATE

(A STAMPED SIGNATURE IS NOT ACCEPTABLE)

☐ Attending ☐ Consulting ☐ Other ordering

UPIN:_____

TELEPHONE #: (___) ___-____

08 16 93

SECTION A: (To be completed by the supplier)

CERTIFICATION TYPE:	Check the appropriate box to indicate if this CMN is the initial certification for this patient or if this is a revised certification.
BENEFICIARY INFORMATION:	Indicate the beneficiary's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the beneficiary's Medicare card and on your claim form.
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to your supplier manual for a complete index.
REPLACEMENT:	If the item billed is a replacement for a previously purchased item, place a check mark in the blank.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
HCPCS CODES:	List all procedure codes for items ordered that require a CMN. Procedure codes that do not require a certification should not be listed on the CMN. If the item ordered is purchased equipment, indicate whether the equipment is covered by a warranty. "Y" denotes that there is a warranty and "N" indicates there is no warranty. If it is covered by a warranty, the length and type of warranty must be indicated.

SECTION B: (To be completed or reviewed and signed by the ordering physician)

DIAGNOSIS:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3).
EXAMINATION DATE:	Indicate the date (MM/DD/YY) the patient was last seen by the ordering physician prior to the beginning of this certification period.
DOB:	Indicate patient's date of birth (MM/DD/YY).
DATE NEEDED:	Indicate the date (MM/DD/YY) the ordered item was initially needed outside the hospital setting. If this certification is a revised certification, also indicate the effective date of the order change.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question within the category of the items ordered, using "Y" for yes, "N" for no, and "D" for does not apply, unless otherwise noted.
PHYSICIAN INFORMATION:	The physician's signature certifies that the item ordered is medically necessary for this patient and that section B was completed or reviewed by the physician. This form must be signed and dated by the physician. Signature and date stamps are not acceptable. The physician must indicate whether he/she is the attending, consulting or other ordering physician by putting a check mark in the appropriate box. Indicate other ordering when you are neither the attending or consulting physician. Refer to your supplier manual for more information.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	The physician must indicate his/her Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	The physician must give a telephone number where he/she can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.
DRESSINGS/SUPPLIES ORDERED:	Describe the type of dressing or urological supplies ordered (use of a brand name optional).
HCPCS COD	In the spaces provided, indicate the appropriate HCPCS code(s) for the item(s) ordered.
FREQUENCY OF CHANGE:	In the space provided, indicate frequency of change for each item ordered. (Refer to medical policy.)

Effective 10/93 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 04.01**

CERTIFICATE OF MEDICAL NECESSITY: ORTHOTICS/LYMPHEDEMA PUMPS/OSTEOGENESIS STIMULATORS/THERAPEUTIC SHOES

SECTION A CERTIFICATION: ☐ **INITIAL** ☐ **REVISED**

PATIENT NAME, ADDRESS, TELEPHONE AND HIC NO.

(_ _ _) _ _ _ - _ _ _ _ HICN_____

SUPPLIER NAME, ADDRESS, TELEPHONE, AND NSC NUMBER

(_ _ _) _ _ _ - _ _ _ _ NSC _____

PLACE OF SERVICE ____ REPLACEMENT ITEM ____

NAME AND ADDRESS OF FACILITY IF APPLICABLE (SEE BACK OF FORM):

HCPCS CODE(S)	WARRANTY	LENGTH	TYPE

SECTION B INFORMATION BELOW TO BE COMPLETED ONLY BY THE PHYSICIAN OR PHYSICIAN'S EMPLOYEE (EXCEPT QUESTIONS 1-6)

DIAGNOSIS (ICD9): ____ ____ ____ ____

DOB ____/____/____

I LAST EXAMINED THIS PATIENT FOR THIS CONDITION ON: ____/____/____ PT. SEX ____ (M OR F)

DATE NEEDED INITIAL ____/____/____ REVISED ____/____/____
EST. LENGTH OF NEED: # OF MONTHS: ____ 1-99 (99 = LIFETIME)

ANSWER QUESTIONS 1-6 FOR ANKLE-FOOT AND KNEE-ANKLE-FOOT ORTHOTICS, 7-11 FOR LYMPHEDEMA PUMPS, 12-15 FOR OSTEOGENESIS STIMULATORS, 16 FOR THERAPEUTIC SHOES. Use Y - Yes, N - No, or D for Does Not Apply unless otherwise noted.

ANKLE-FOOT/KNEE-ANKLE-FOOT ORTHOTICS

[ ] 1. Does the patient have weakness or deformity of the foot and ankle which requires stabilization to achieve functional benefit?

[ ] 2. Does the patient have weakness or deformity of the knee which requires stabilization to achieve functional benefit?

[ ] 3. Is the condition expected to exist for more than 6 months?

[ ] 4. Is the patient unable to be fitted with a custom-fitted orthosis?

[ ] 5. Is there a need to control the knee, ankle, or foot in more than one plane?

[ ] 6. Does the patient have a documented neurological, circulatory, or orthopedic status (e.g. a healing fracture lacking normal anatomical integrity or anthropometric proportions) that requires custom fabricating over a model to prevent tissue injury?

LYMPHEDEMA PUMP

[ ] 7. Does the patient have a malignant tumor with obstruction of the lymphatic drainage of an extremity?

[ ] 8. Has the patient had surgery or radiation that interrupted normal lymphatic drainage or is there a congenital abnormality of lymphatic drainage?

[ ] 9. Is the device prescribed for the treatment of chronic venous insufficiency with edema and/or venous ulcers?

[ ] 10. Is there postinflammatory lymphatic obstruction?

[ ] 11. Have suitable instructions as to the pressure to be used and the frequency and duration of use been provided?

OSTEOGENESIS STIMULATOR

[ ] 12. Does the patient have a nonunion of a long bone fracture?

[ ] 13. Does the patient have a failed fusion?

[ ] 14. Does the patient have a congenital pseudarthrosis?

____ 15. How many months ago did the patient sustain the long bone fracture being treated or have the fusion that has failed?
(ENTER THE NUMBER OF MONTHS 1 - 99)

THERAPEUTIC SHOES

[ ] 16. Are you the physician who is managing the patient's systemic diabetic condition?

I certify the medical necessity of these items for this patient. Section B of this form and any statement on my letterhead attached hereto has been completed by me, or by my employee and reviewed by me (except questions 1-6, which do not require physician completion but do require physician review). The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN NAME, ADDRESS

_____ __/__/__
PHYSICIAN'S SIGNATURE: DATE
(A STAMPED SIGNATURE IS NOT ACCEPTABLE)

☐ Attending ☐ Consulting ☐ Other ordering

UPIN:_____

TELEPHONE #: (_ _ _) _ _ _ - _ _ _ _

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SECTION A: (To be completed by the supplier)

CERTIFICATION TYPE:	Check the appropriate box to indicate if this CMN is the initial certification for this patient or if this is a revised certification.
BENEFICIARY INFORMATION:	Indicate the beneficiary's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the beneficiary's Medicare card and on your claim form.
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to your supplier manual for a complete index.
REPLACEMENT:	If the item billed is a replacement for a previously purchased item, place a check mark in the blank.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
HCPCS CODES:	List all procedure codes for items ordered that require a CMN. Procedure codes that do not require a certification should not be listed on the CMN. If the item ordered is purchased equipment, indicate whether the equipment is covered by a warranty. "Y" denotes that there is a warranty and "N" indicates there is no warranty. If it is covered by a warranty, the length and type of warranty must be indicated.

SECTION B: (To be completed by the physician or physician's employee, except for questions 1-6)

DIAGNOSIS:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3).
EXAMINATION DATE:	Indicate the date (MM/DD/YY) the patient was last seen by the ordering physician prior to the beginning of this certification period.
DOB:	Indicate patient's date of birth (MM/DD/YY).
DATE NEEDED:	Indicate the date (MM/DD/YY) the ordered item was initially needed outside the hospital setting. If this certification is a revised certification, also indicate the effective date of the order change.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question within the category of items ordered, using "Y" for yes, "N" for no, and "D" for does not apply, unless otherwise noted. Questions 1-6 (Ankle-Foot/Knee-Ankle-Foot Orthotics) do not require physician completion, but do require physician review.
PHYSICIAN INFORMATION:	The physician's signature certifies that the item ordered is medically necessary for this patient and that section B was completed or reviewed by the physician. This form must be signed and dated by the physician. Signature and date stamps are not acceptable. The physician must indicate whether he/she is the attending, consulting or other ordering physician by putting a check mark in the appropriate box. Indicate other ordering when you are neither the attending or consulting physician. Refer to your supplier manual for more information.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	The physician must indicate his/her Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	The physician must give a telephone number where he/she can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/93 DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER DMERC 03.01

CERTIFICATE OF MEDICAL NECESSITY: RESPIRATORY EQUIPMENT

SECTION A CERTIFICATION: ☐ INITIAL ☐ REVISED

PATIENT NAME, ADDRESS, TELEPHONE AND HIC NO.

(___) ___ - ____ HICN_____

SUPPLIER NAME, ADDRESS, TELEPHONE, AND NSC NUMBER

(___) ___ - ____ NSC _____

PLACE OF SERVICE ____ REPLACEMENT ITEM ____

NAME AND ADDRESS OF FACILITY IF APPLICABLE (SEE BACK OF FORM):

HCPCS CODE(S)	WARRANTY	LENGTH	TYPE

SECTION B INFORMATION BELOW TO BE COMPLETED ONLY BY THE PHYSICIAN OR PHYSICIAN'S EMPLOYEE

DIAGNOSIS (ICD9): ____ ____ ____ ____

DOB ___/___/___

I LAST EXAMINED THIS PATIENT FOR THIS CONDITION ON: ___/___/___ PT. SEX ____ (M OR F)

DATE NEEDED INITIAL ___/___/___ REVISED ___/___/___
EST. LENGTH OF NEED: # OF MONTHS: ___ 1-99 (99 = LIFETIME)

ANSWER QUESTIONS 12-14 FOR CPAP, 18-22 FOR SUCTION PUMP. Use Y - Yes, N - No, or D for Does Not Apply unless otherwise noted.

1. Reserved for future use.
2. Reserved for future use.
3. Reserved for future use.
4. Reserved for future use.
5. Reserved for future use.
6. Reserved for future use.
7. Reserved for future use.
8. Reserved for future use.
9. Reserved for future use.
10. Reserved for future use.
11. Reserved for future use.

CONTINUOUS POSITIVE AIRWAY PRESSURE SYSTEM (CPAP)

____ 12. How many episodes of apnea lasting greater than 10 seconds does the patient have during 6-7 hours of recorded sleep? (Number of episodes).

[ ] 13. Is surgery a likely alternative to CPAP?

[ ] 14. Does the patient have obstructive sleep apnea?

15. Reserved for future use.

16. Reserved for future use.

17. Reserved for future use.

SUCTION PUMP

[ ] 18. Does the patient have difficulty raising and clearing secretions?

[ ] 19. Does the patient have cancer or surgery of the throat or mouth?

[ ] 20. Does patient have dysfunction of the swallowing muscles?

[ ] 21. Is the patient unconscious or in an obtunded state?

[ ] 22. Does patient have a tracheostomy?

I certify the medical necessity of these items for this patient. Section B of this form and any statement on my letterhead attached hereto has been completed by me, or by my employee and reviewed by me. The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN NAME, ADDRESS

PHYSICIAN'S SIGNATURE: _____ DATE ___/___/___
(A STAMPED SIGNATURE IS NOT ACCEPTABLE)

☐ Attending ☐ Consulting ☐ Other ordering

UPIN: _____

TELEPHONE #: (___) ___ - ____

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SECTION A: (To be completed by the supplier)

CERTIFICATION TYPE:	Check the appropriate box to indicate if this CMN is the initial certification for this patient or if this is a revised certification.
BENEFICIARY INFORMATION:	Indicate the beneficiary's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the beneficiary's Medicare card and on your claim form.
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to your supplier manual for a complete index.
REPLACEMENT:	If the item billed is a replacement for a previously purchased item, place a check mark in the blank.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
HCPCS CODES:	List all procedure codes for items ordered that require a CMN. Procedure codes that do not require a certification should not be listed on the CMN. If the item ordered is purchased equipment, indicate whether the equipment is covered by a warranty. "Y" denotes that there is a warranty and "N" indicates there is no warranty. If it is covered by a warranty, the length and type of warranty must be indicated.

SECTION B: (To be completed by the physician or physician's employee)

DIAGNOSIS:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3).
EXAMINATION DATE:	Indicate the date (MM/DD/YY) the patient was last seen by the ordering physician prior to the beginning of this certification period.
DOB:	Indicate patient's date of birth (MM/DD/YY).
DATE NEEDED:	Indicate the date (MM/DD/YY) the ordered item was initially needed outside the hospital setting. If this certification is a revised certification, also indicate the effective date of the order change.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question within the category of the items ordered, using "Y" for yes, "N" for no, and "D" for does not apply, unless otherwise noted.
PHYSICIAN INFORMATION:	The physician's signature certifies that the item ordered is medically necessary for this patient and that section B was completed or reviewed by the physician. This form must be signed and dated by the physician. Signature and date stamps are not acceptable. The physician must indicate whether he/she is the attending, consulting or other ordering physician by putting a check mark in the appropriate box. Indicate other ordering when you are neither the attending or consulting physician. Refer to your supplier manual for more information.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	The physician must indicate his/her Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	The physician must give a telephone number where he/she can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/93 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 02.01

CERTIFICATE OF MEDICAL NECESSITY: MANUAL/MOTORIZED WHEELCHAIRS

SECTION A **CERTIFICATION:** ☐ INITIAL ☐ REVISED

PATIENT NAME, ADDRESS, TELEPHONE AND HIC NO.

(___) ___ - ____ HICN_____

SUPPLIER NAME, ADDRESS, TELEPHONE, AND NSC NUMBER

(___) ___ - ____ NSC _____

PLACE OF SERVICE ____ REPLACEMENT ITEM ____

NAME AND ADDRESS OF FACILITY IF APPLICABLE (SEE BACK OF FORM):

HCPCS CODE(S)	WARRANTY	LENGTH	TYPE

SECTION B **INFORMATION BELOW TO BE COMPLETED ONLY BY THE PHYSICIAN OR PHYSICIAN'S EMPLOYEE**

DIAGNOSIS (ICD9): ____ ____ ____ ____

PT. HT. ____ (IN.) PT. WT. ____ (LBS) DOB ____/____/____

I LAST EXAMINED THIS PATIENT FOR THIS CONDITION ON: ____/____/____ PT. SEX ____ (M OR F)

DATE NEEDED INITIAL ____/____/____ REVISED ____/____/____
EST. LENGTH OF NEED: # OF MONTHS: ____ 1-99 (99 = LIFETIME)

ANSWER QUESTIONS 1-4 FOR MOTORIZED WHEELCHAIR BASE, 4, 18-22 FOR MANUAL WHEELCHAIR BASE, 4-18 FOR WHEELCHAIR OPTIONS.
Use Y - Yes, N - No, or D for Does Not Apply unless otherwise noted.

[ ] 1. Does the patient have severe weakness of the upper extremities due to a neurologic or muscular disease/condition?

[ ] 2. Is the patient unable to operate a wheelchair manually?

[ ] 3. Is the patient capable of safely operating the controls of a power wheelchair?

[ ] 4. Would the patient be bed or chair confined without the use of a wheelchair?

[ ] 5. Does patient have quadriplegia?

[ ] 6. Does patient have a fixed hip angle?

[ ] 7. Does patient have a trunk cast or brace that requires a reclining back feature for positioning?

[ ] 8. Does the patient have a cast or brace which prevents 90 degree flexion of the knee?

[ ] 9. Does patient have a musculoskeletal condition that prevents 90 degree flexion at the knee?

[ ] 10. Does patient have excessive extensor tone of the trunk muscles?

[ ] 11. Does patient have weak neck muscles requiring support?

[ ] 12. Does patient have weak upper body muscles, upper body insta-bility or muscle spasticity?

[ ] 13. Does patient have use of only one hand/arm and the condition is expected to last for 6 months or more?

[ ] 14. Is there hemiplegia or uncontrolled arm movements?

[ ] 15. Does patient have a need for arm height different than that available using non-adjustable arms?

[ ] 16. Does the patient need to rest in a recumbent position two or more times during the day?

[ ] 17. Is transfer between bed and wheelchair very difficult?

____ 18. How many hours per day does the patient usually spend in the wheelchair? (round up to next hour, e.g., for 3 1/2 hours, use 4) use 1-24.

[ ] 19. Is the patient able to place his/her feet on the ground for propulsion in a standard wheelchair?

[ ] 20. Is the patient able to self-propel in a standard wheelchair?

[ ] 21. Reserved for future use.

[ ] 22. Can/does patient self-propel in a lightweight wheelchair?

I certify the medical necessity of these items for this patient. Section B of this form and any statement on my letterhead attached hereto has been completed by me, or by my employee and reviewed by me. The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN NAME, ADDRESS

_____ __/__/__
PHYSICIAN'S SIGNATURE: DATE
(A STAMPED SIGNATURE IS NOT ACCEPTABLE)

☐ Attending ☐ Consulting ☐ Other ordering

UPIN:_____

TELEPHONE #: (___) ___ - ____

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SECTION A: (To be completed by the supplier)

CERTIFICATION TYPE:	Check the appropriate box to indicate if this CMN is the initial certification for this patient or if this is a revised certification.
BENEFICIARY INFORMATION:	Indicate the beneficiary's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the beneficiary's Medicare card and on your claim form.
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to your supplier manual for a complete index.
REPLACEMENT:	If the item billed is a replacement for a previously purchased item, place a check mark in the blank.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
HCPCS CODES:	List all procedure codes for items ordered that require a CMN. Procedure codes that do not require a certification should not be listed on the CMN. If the item ordered is purchased equipment, indicate whether the equipment is covered by a warranty. "Y" denotes that there is a warranty and "N" indicates there is no warranty. If it is covered by a warranty, the length and type of warranty must be indicated.

SECTION B: (To be completed by the physician or physician's employee)

DIAGNOSIS:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3).
EXAMINATION DATE:	Indicate the date (MM/DD/YY) the patient was last seen by the ordering physician prior to the beginning of this certification period.
PT. HT., PT. WT., DOB:	Indicate the patient's height in inches and weight in pounds (when required by individual policy) Indicate patient's date of birth (MM/DD/YY).
DATE NEEDED:	Indicate the date (MM/DD/YY) the ordered item was initially needed outside the hospital setting. If this certification is a revised certification, also indicate the effective date of the order change.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question within the category of the items ordered, using "Y" for yes, "N" for no, and "D" for does not apply, unless otherwise noted.
PHYSICIAN INFORMATION:	The physician's signature certifies that the item ordered is medically necessary for this patient and that section B was completed or reviewed by the physician. This form must be signed and dated by the physician. Signature and date stamps are not acceptable. The physician must indicate whether he/she is the attending, consulting or other ordering physician by putting a check mark in the appropriate box. Indicate other ordering when you are neither the attending or consulting physician. Refer to your supplier manual for more information.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	The physician must indicate his/her Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	The physician must give a telephone number where he/she can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/93 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 01.01**

CERTIFICATE OF MEDICAL NECESSITY: HOSPITAL BEDS/SUPPORT SURFACES

SECTION A **CERTIFICATION:** ☐ INITIAL ☐ REVISED

PATIENT NAME, ADDRESS, TELEPHONE AND HIC NO.

(___) ___-____ HICN _____

SUPPLIER NAME, ADDRESS, TELEPHONE, AND NSC NUMBER

(___) ___-____ NSC _____

PLACE OF SERVICE ____ REPLACEMENT ITEM ____

NAME AND ADDRESS OF FACILITY IF APPLICABLE (SEE BACK OF FORM):

HCPCS CODE(S)	WARRANTY	LENGTH	TYPE

SECTION B **INFORMATION BELOW TO BE COMPLETED ONLY BY THE PHYSICIAN OR PHYSICIAN'S EMPLOYEE**

DIAGNOSIS (ICD9): _____ _____ _____ _____

DOB ____/____/____

I LAST EXAMINED THIS PATIENT FOR THIS CONDITION ON: ____/____/____ PT. SEX ____ (M OR F)

DATE NEEDED INITIAL ____/____/____ REVISED ____/____/____

EST. LENGTH OF NEED: # OF MONTHS: ____ 1-99 (99 = LIFETIME)

ANSWER QUESTIONS 1-7 FOR HOSPITAL BEDS, 12-13 AND 21 FOR ALTERNATING PRESSURE PADS OR MATTRESSES, 13-22 FOR AIR-FLUIDIZED BEDS Use Y - Yes, N - No, or D for Does Not Apply unless otherwise noted.

[ ] 1. Does the patient require positioning of the body in ways not feasible with an ordinary bed due to a medical condition which is expected to last at least one month?

2. Reserved for future use.

[ ] 3. Does the patient require, for the alleviation of pain, positioning of the body in ways not feasible with an ordinary bed?

[ ] 4. Does the patient require the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or aspiration?

[ ] 5. Does the patient require traction which can only be attached to a hospital bed?

[ ] 6. Does the patient require a bed height different than a fixed height hospital bed to permit transfers to chair, wheelchair, or standing position?

[ ] 7. Does the patient require frequent changes in body position and/or have an immediate need for a change in body position?

[ ] 8. Reserved for future use.

9. Reserved for future use.

[ ] 10. Reserved for future use.

[ ] 11. Reserved for future use.

[ ] 12. Is the patient highly susceptible to decubitus ulcers?

[ ] 13. Are you supervising the use of the device?

[ ] 14. Does the patient have coexisting pulmonary disease?

[ ] 15. Has a conservative treatment program been tried without success?

[ ] 16. Was a comprehensive assessment performed after failure of conservative treatment?

[ ] 17. Is the home electric system sufficient for the anticipated increase in energy consumption?

[ ] 18. Is structural support adequate to support the air-fluidized bed?

[ ] 19. Are open, moist dressings used for the treatment of the patient?

[ ] 20. Is there a trained fulltime caregiver to assist the patient and manage all aspects involved with the use of the bed?

21. Provide the stage and size of each pressure area/ulcer necessitating the use of the overlay, mattress or bed.

	Pressure area/Ulcer #1	#2	#3
Stage:	____	____	____
Max Length (cm):	____	____	____
Max Width (cm):	____	____	____

___ 22. Over the past month, the patient's ulcer(s) has/have:

1) improved 2) remained the same 3) worsened

I certify the medical necessity of these items for this patient. Section B of this form and any statement on my letterhead attached hereto has been completed by me, or by my employee and reviewed by me. The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN NAME, ADDRESS

PHYSICIAN'S SIGNATURE: _____ ___/___/___ DATE

(A STAMPED SIGNATURE IS NOT ACCEPTABLE)

☐ Attending ☐ Consulting ☐ Other ordering

UPIN: _____

TELEPHONE #: (___) ___-____

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SECTION A: (To be completed by the supplier)

CERTIFICATION TYPE:	Check the appropriate box to indicate if this CMN is the initial certification for this patient or if this is a revised certification.
BENEFICIARY INFORMATION:	Indicate the beneficiary's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the beneficiary's Medicare card and on your claim form.
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to your supplier manual for a complete index.
REPLACEMENT:	If the item billed is a replacement for a previously purchased item, place a check mark in the blank.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
HCPCS CODES:	List all procedure codes for items ordered that require a CMN. Procedure codes that do not require a certification should not be listed on the CMN. If the item ordered is purchased equipment, indicate whether the equipment is covered by a warranty. "Y" denotes that there is a warranty and "N" indicates there is no warranty. If it is covered by a warranty, the length and type of warranty must be indicated.

SECTION B: (To be completed by the physician or physician's employee)

DIAGNOSIS:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3).
EXAMINATION DATE:	Indicate the date (MM/DD/YY) the patient was last seen by the ordering physician prior to the beginning of this certification period.
DOB:	Indicate patient's date of birth (MM/DD/YY).
DATE NEEDED:	Indicate the date (MM/DD/YY) the ordered item was initially needed outside the hospital setting. If this certification is a revised certification, also indicate the effective date of the order change.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question within the category of the items ordered, using "Y" for yes, "N" for no, and "D" for does not apply, unless otherwise noted.
PHYSICIAN INFORMATION:	The physician's signature certifies that the item ordered is medically necessary for this patient and that section B was completed or reviewed by the physician. This form must be signed and dated by the physician. Signature and date stamps are not acceptable. The physician must indicate whether he/she is the attending, consulting or other ordering physician by putting a check mark in the appropriate box. Indicate other ordering when you are neither the attending or consulting physician. Refer to your supplier manual for more information.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	The physician must indicate his/her Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	The physician must give a telephone number where he/she can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

12.7 Certificate of Medical Necessity Forms

The Certificate of Medical Necessity forms are numbered in the upper right-hand corner. These numbers are referred to in the documentation section of the policies to which the CMN applies. The last two digits of the CMN form number (after the decimal point) refer to the version number. As of this printing, the most current CMN form version numbers are ".01." Over time, these version numbers may change on the different forms, based on medical policy changes. You will be notified when new versions of the CMN forms are required.

These CMNs may be photocopied and used for submission to your Region A DMERC for processing. ***The instructions vary with the form. Read them carefully.*** On the back of each CMN are instructions about completing the form. The bank of the form need not be copied for submission.

Other questions concerning completion of these forms may be addressed to Supplier Services at 1-800-842-2563.

CMN Number	*Policy*	*Policy Page Numbers*
DMERC 01.01	Hospital Beds	13-59
	Support Surfaces	13-96
DMERC 02.01	Motorized Wheelchair Base	13-66
	Manual Wheelchair Base	13-69
	Wheelchair Options	13-74
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Power Operated Wheelchair and Wheelchair with other special features	covered if patient's condition is such that a wheelchair is medically necessary and the patient is unable to operate the wheelchair manually. Any claim involving a power wheelchair or a wheelchair with other special features should be referred for medical consultation since payment for the special features is limited to those which are medically required because of the patient's condition. *Note:* A power-operated vehicle that may appropriately be used as a wheelchair can be covered.
Whirl-A-Bath	deny-(see Portable Whirlpool Pumps)
Whirl-O-Matic	deny-(see Portable Whirlpool Pumps)
Whirlpool Bath Equipment (standard)	covered if patient is homebound and has a condition for which the whirlpool bath can be expected to provide substantial therapeutic benefit justifying its cost. Where patient is not homebound but has such a condition, payment is restricted to the cost of providing the services elsewhere, e.g., an outpatient department of a participating hospital, if that alternative is less costly. In all cases, refer claim to medical staff for a determination.
Whirlpool Pumps	deny-(see Portable Whirlpool Pumps)

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 01.02A**

Certificate Of Medical Necessity: HOSPITAL BEDS **PAGE 1 OF 2**

SECTION A **Certification Type/Date:** **INITIAL** ___/___/___ **REVISED** ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(_ _ _) _ _ _ - _ _ _ _ HICN _____	(_ _ _) _ _ _ - _ _ _ _ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___; Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	

HCPCS CODES	REPLACEMENT (*check if applicable*)	WARRANTY (*see reverse*) Length (months)	Type (1-4)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ 1-99 (99=LIFETIME) | **DIAGNOSIS CODES (ICD-9): _____ _____ _____ _____**

ANSWERS	ANSWER QUESTIONS 1, AND 3-7 FOR HOSPITAL BEDS (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply)
	QUESTION 2 RESERVED FOR OTHER OR FUTURE USE.
Y N D	1. Does the patient require positioning of the body in ways not feasible with an ordinary bed due to a medical condition which is expected to last at least one month?
Y N D	3. Does the patient require, for the alleviation of pain, positioning of the body in ways not feasible with an ordinary bed?
Y N D	4. Does the patient require the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or aspiration?
Y N D	5. Does the patient require traction which can only be attached to a hospital bed?
Y N D	6. Does the patient require a bed height different than a fixed height hospital bed to permit transfers to chair, wheelchair, or standing position?
Y N D	7. Does the patient require frequent changes in body position and/or have an immediate need for a change in body position?

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	
	PHYSICIAN'S UPIN: _____
	PHYSICIAN'S TELEPHONE #: (_ _ _) _ _ _ - _ _ _ _

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 01.02A

Certificate Of Medical Necessity: HOSPITAL BEDS PAGE 2 OF 2

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; (2) Narrative description of all items, accessories and options ordered; (3) Supplier's charge; and (4) Medicare Fee Schedule Allowance for each item, accessory, and option.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 01.02B

Certificate Of Medical Necessity: SUPPORT SURFACES PAGE 1 OF 2

SECTION A **Certification Type/Date:** **INITIAL** ___/___/___ **REVISED** ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(___)___-____ HICN _____	(___)___-____ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___; Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	HCPCS CODES / REPLACEMENT (*check if applicable*) / WARRANTY (*see reverse*) Length (months) / Type (1-4)

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ **1-99 (99=LIFETIME)** **DIAGNOSIS CODES (ICD-9):** _____ _____ _____ _____

ANSWERS	ANSWER QUESTIONS 12,13 & 21 FOR ALTERNATING PRESSURE PADS OR MATTRESSES; 13-22 FOR AIR FLUIDIZED BEDS (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply, Unless Otherwise Noted)
	QUESTIONS 1-11, 17 AND 18 ARE RESERVED FOR OTHER OR FUTURE USE.
Y N D	12. Is the patient highly susceptible to decubitus ulcers?
Y N D	13. Are you supervising the use of the device?
Y N D	14. Does the patient have coexisting pulmonary disease?
Y N D	15. Has a conservative treatment program been tried without success?
Y N D	16. Was a comprehensive assessment performed after failure of conservative treatment?
Y N D	19. Are open, moist dressings used for the treatment of the patient?
Y N D	20. Is there a trained full-time caregiver to assist the patient and manage all aspects involved with the use of the bed?
	21. Provide the stage and size of each pressure ulcer necessitating the use of the overlay, mattress or bed. If the patient is highly susceptible to decubitus ulcers, but currently has no ulcer present, place a "9" under ulcer #1.
	Pressure Ulcer / Ulcer # 1 / Ulcer # 2 / Ulcer # 3
	Stage: _____ _____ _____
	Max. Length (cm): _____ _____ _____
	Max. Width (cm): _____ _____ _____
1 2 3	22. Over the past month, the patient's ulcer(s) has/have: 1) Improved 2) Remained the same 3) Worsened?

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	
	PHYSICIAN'S UPIN: _____
	PHYSICIAN'S TELEPHONE #: (___)___-____

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 01.02B

Certificate Of Medical Necessity: SUPPORT SURFACES PAGE 2 OF 2

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories and options ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, and option.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving (1) narrative diagnoses given by physician; (2) a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; (3) the supplier's charge for each item, option, accessory, supply and drug; and (4) the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that (1) the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; (2) Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; (3) the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 02.02A

Certificate Of Medical Necessity: MOTORIZED WHEELCHAIRS PAGE 1 OF 2

SECTION A **Certification Type/Date:** INITIAL ___/___/___ REVISED ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(_ _ _) _ _ _ - _ _ _ _ HICN _____	(_ _ _) _ _ _ - _ _ _ _ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___; HT. _____ (in.) (*optional*); WT. _____ (lbs.); Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	HCPCS CODES / REPLACEMENT (*check if applicable*) / WARRANTY (*see reverse*) Length (months) / Type (1-4)
	_____ _____ _____ _____
	_____ _____ _____ _____
	_____ _____ _____ _____
	_____ _____ _____ _____

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ 1-99 (99=LIFETIME) | **DIAGNOSIS CODES (ICD-9): _____ _____ _____ _____**

ITEM ADDRESSED	ANSWERS	ANSWER QUESTIONS 1-4 FOR MOTORIZED WHEELCHAIR BASE, 4-18 FOR WHEELCHAIR OPTIONS/ACCESSORIES. (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply, Unless Otherwise Noted)
		Questions 3, 9, 11 - 14, and 17, reserved for other or future use.
Motorized Whlchr Base	Y N D	1. Does the patient have severe weakness of the upper extremities due to a neurologic, muscular, or cardiopulmonary disease/condition?
Motorized Whlchr Base	Y N D	2. Have all types of manual wheelchairs been considered and ruled out?
Motorized Whlchr Base and Accessories	Y N D	4. Does the patient require and use a wheelchair to move around in their residence?
Reclining Back	Y N D	5. Does the patient have quadriplegia?
Reclining Back	Y N D	6. Does the patient have a fixed hip angle?
Reclining Back	Y N D	7. Does the patient have a trunk cast or brace that requires a reclining back feature for positioning?
Elevating Leg Rest	Y N D	8. Does the patient have a cast, brace or musculoskeletal condition, which prevents 90 degree flexion of the knee, or does the patient have significant edema of the lower extremities that requires an elevating leg rest?
Reclining Back	Y N D	10. Does the patient have excessive extensor tone of the trunk muscles?
Adjustable Height Armrest	Y N D	15. Does the patient have a need for arm height different than that available using non-adjustable arms?
Reclining Back	Y N D	16. Does the patient need to rest in a recumbent position two or more times during the day?
Reclining Back; Adjustable HT. Armrest	_____	18. How many hours per day does the patient usually spend in the wheelchair? (1-24) (Round up to the next hour)

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	
	PHYSICIAN'S UPIN: _____
	PHYSICIAN'S TELEPHONE #: (_ _ _) _ _ _ - _ _ _ _

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked, "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
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SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
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EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
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UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 02.02A

Certificate Of Medical Necessity: MOTORIZED WHEELCHAIRS PAGE 2 OF 2

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories and options ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, and option.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

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PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving (1) narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 02.02B

Certificate Of Medical Necessity: MANUAL WHEELCHAIRS PAGE 1 OF 2

SECTION A **Certification Type/Date:** INITIAL __/__/__ REVISED __/__/__

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER

(_ _ _) _ _ _ - _ _ _ _ HICN _____

SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER

(_ _ _) _ _ _ - _ _ _ _ NSC # _____

PLACE OF SERVICE _____

NAME and ADDRESS of FACILITY if applicable (see reverse):

PT DOB ___/___/___; HT. _____ (in.) (*optional*); WT. _____ (lbs.); Sex ____ (M/F)

HCPCS CODES	REPLACEMENT (*check if applicable*)	WARRANTY (*see reverse*) Length (months)	Type (1-4)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ **1-99 (99=LIFETIME)** **DIAGNOSIS CODES (ICD-9):** _____ _____ _____ _____

ITEM ADDRESSED	ANSWERS	ANSWER QUESTIONS 4 AND 18-22 FOR MANUAL WHEELCHAIR BASE; 4-18 FOR WHEELCHAIR OPTIONS/ACCESSORIES. (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply, Unless Otherwise Noted)
		Questions 1 - 3, 9, 11 - 14, 17, 19, and 21 reserved for other or future use.
Manual Whlchr Base And All Accessories	Y N D	4. Does the patient require and use a wheelchair to move around in their residence?
Reclining Back	Y N D	5. Does the patient have quadriplegia?
Reclining Back	Y N D	6. Does the patient have a fixed hip angle?
Reclining Back	Y N D	7. Does the patient have a trunk cast or brace that requires a reclining back feature for positioning?
Elevating Leg Rest	Y N D	8. Does the patient have a cast, brace or musculoskeletal condition, which prevents 90 degree flexion of the knee, or does the patient have significant edema of the lower extremities that requires an elevating leg rest?
Reclining Back	Y N D	10. Does the patient have excessive extensor tone of the trunk muscles?
Adjustable HT. Armrest	Y N D	15. Does the patient have a need for arm height different than that available using non-adjustable arms?
Reclining Back	Y N D	16. Does the patient need to rest in a recumbent position two or more times during the day?
Reclining Back; Adjustable HT. Armrest; Any Type Ltwt. Whlchr	_____	18. How many hours per day does the patient usually spend in the wheelchair? (1-24) (Round up to the next hour)
Any Type Ltwt. Whlchr	Y N D	20. Is the patient able to adequately self-propel (without being pushed) in a standard weight manual wheelchair?
Any Type Ltwt. Whlchr	Y N D	22. If the answer to question #20 is "No", would the patient be able to adequately self-propel (without being pushed) in the wheelchair which has been ordered?

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)

PHYSICIAN'S UPIN: _____

PHYSICIAN'S TELEPHONE #: (_ _ _) _ _ _ - _ _ _ _

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked, "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 02.02B

Certificate Of Medical Necessity: MANUAL WHEELCHAIRS PAGE 2 OF 2

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories and options ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, and option.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 03.02**

Certificate Of Medical Necessity: CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) **PAGE 1 OF 2**

SECTION A **Certification Type/Date:** **INITIAL ___/___/___ REVISED ___/___/___**

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(_ _ _) _ _ _ - _ _ _ _ HICN _____	(_ _ _) _ _ _ - _ _ _ _ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___ Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse)	HCPCS CODES / REPLACEMENT (*check if applicable*) / WARRANTY (*see reverse*) Length (months) / Type (1-4)

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ 1-99 (99=LIFETIME) **DIAGNOSIS CODES (ICD-9): _____ _____ _____ _____**

ANSWERS	ANSWER QUESTIONS 12 AND 14 FOR CPAP (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply, Unless Otherwise Noted)
	Questions 1 - 11, and 13, reserved for other or future use.
_ _	12. How many episodes of apnea lasting greater than 10 seconds does the patient have during 6-7 hours of recorded sleep? (Number of episodes) (If greater than 99, enter 99.)
Y N D	14. Does the patient have obstructive sleep apnea?

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	
	PHYSICIAN'S UPIN: _____
	PHYSICIAN'S TELEPHONE #: (_ _ _) _ _ _ - _ _ _ _

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 03.02**

Certificate Of Medical Necessity: CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) **PAGE 2 OF 2**

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories, options and supplies ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, option and supply.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 04.02B

Certificate Of Medical Necessity: LYMPHEDEMA PUMPS PAGE 1 OF 2

SECTION A **Certification Type/Date:** INITIAL ___/___/___ REVISED ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(___) ___-____ HICN _____	(___) ___-____ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___; Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	HCPCS CODES / REPLACEMENT (check if applicable) / WARRANTY (see reverse) Length (months) / Type (1-4)

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ 1-99 (99=LIFETIME) **DIAGNOSIS CODES (ICD-9): _____ _____ _____ _____**

ANSWERS	ANSWER QUESTIONS 7-11 FOR LYMPHEDEMA PUMP (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply)
	QUESTIONS 1 - 6, reserved for other or future use.
Y N D	7. Does the patient have a malignant tumor with obstruction of the lymphatic drainage of an extremity?
Y N D	8. Has the patient had surgery or radiation that interrupted normal lymphatic drainage or is there a congenital abnormality of lymphatic drainage?
Y N D	9. Is the device prescribed for the treatment of chronic venous insufficiency with edema and/or venous ulcers?
Y N D	10. Is there intractable lymphedema?
Y N D	11. Has the physician prescribed the pressures to be used and the frequency and duration of use of this device?

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	**PHYSICIAN'S UPIN:** _____
	PHYSICIAN'S TELEPHONE #: (___) ___-____

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked, "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 04.02B**

Certificate Of Medical Necessity: LYMPHEDEMA PUMPS **PAGE 2 OF 2**

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories and options ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, and option.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 04.02C**

Certificate Of Medical Necessity: OSTEOGENESIS STIMULATOR **PAGE 1 OF 2**

SECTION A **Certification Type/Date:** **INITIAL** ___/___/___ **REVISED** ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(___)___-____ HICN _____	(___)___-____ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___, Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	HCPCS CODES / REPLACEMENT (*check if applicable*) / WARRANTY (*see reverse*) Length (months) / Type (1-4)
	_____ _____ _____ _____
	_____ _____ _____ _____
	_____ _____ _____ _____
	_____ _____ _____ _____

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ 1-99 (99=LIFETIME) **DIAGNOSIS CODES (ICD-9): _____ _____ _____ _____**

ANSWERS	ANSWER QUESTIONS 12-15 FOR OSTEOGENESIS STIMULATOR. (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply, Unless Otherwise Noted)
-	QUESTIONS 1 - 11, and 16, reserved for other or future use.
Y N D	12. Does the patient have a non-union of a long-bone fracture?
Y N D	13. Does the patient have a failed fusion?
Y N D	14. Does the patient have a congenital pseudoarthrosis?
_____	15. How many months ago did the patient sustain the long-bone fracture being treated or have the fusion that has failed? (Enter number of months 1-99)

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	
	PHYSICIAN'S UPIN: _____
	PHYSICIAN'S TELEPHONE #: (___)___-____

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked, "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 04.02C

Certificate Of Medical Necessity: OSTEOGENESIS STIMULATOR PAGE 2 OF 2

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories and options ordered; **(3)** Supplier's charge: and **(4)** Medicare Fee Schedule Allowance for each item, accessory, and option.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 06.02**

Certificate Of Medical Necessity: TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS) **PAGE 1 OF 2**

SECTION A **Certification Type/Date:** **INITIAL** ___/___/___ **REVISED** ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(___) ___-____ HICN _____	(___) ___-____ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___; Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	HCPCS CODES / REPLACEMENT (*check if applicable*) / WARRANTY (*see reverse*) Length (months) / Type (1-4)
	_____ _____ _____ _____
	_____ _____ _____ _____
	_____ _____ _____ _____
	_____ _____ _____ _____

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ **1-99 (99=LIFETIME)** **DIAGNOSIS CODES (ICD-9):** _____ _____ _____ _____

ANSWERS	ANSWER QUESTIONS 1 - 6 FOR RENTAL OF TENS, AND 3 - 12 FOR PURCHASE OF TENS. (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply, Unless Otherwise Noted)
Y N D	1. Does the patient have acute post-operative pain?
___/___/___	2. What is the date of surgery resulting in acute post-operative pain?
Y N D	3. Does the patient have chronic, intractable pain?
[_____ months]	4. How long has the patient had intractable pain? (Enter number of months, 1 - 99.)
1 2 3 4 5	5. Is the TENS unit being prescribed for any of the following conditions? (Circle appropriate number) 1 - Headache 2 - Visceral abdominal pain 3 - Pelvic pain 4 - Temporomandibular joint (TMJ) pain 5 - None of the above
Y N D	6. Is there documentation in the medical record of multiple medications and/or other therapies that have been tried and failed?
Y N D	7. Has the patient received a TENS trial?
Began/Ended ___/___/___ ___/___/___	8. What are the dates that trial of TENS unit began and ended?
___/___/___	9. What is the date that you reevaluated the patient at the end of the trial period?
1 2 3	10. How often has the patient been using the TENS? (Circle appropriate number) 1 = Daily 2 = 3 to 6 days per week 3 = 2 or less days per week
Y N D	11. Do you and the patient agree that there has been a significant improvement in the pain and that long term use of a TENS is warranted?
2 4	12. Number of TENS leads (i.e., separate electrodes) routinely needed and used by the patient at any one time: (Circle appropriate number) 2 = 2 leads 4 = 4 leads

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	
	PHYSICIAN'S UPIN: _____
	PHYSICIAN'S TELEPHONE #: (___) ___-____

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked, "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 06.02**

Certificate Of Medical Necessity: TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS) **PAGE 2 OF 2**

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories, options and supplies ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, option and supply.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 07.02A**

Certificate Of Medical Necessity: SEAT LIFT MECHANISM **PAGE 1 OF 2**

SECTION A **Certification Type/Date:** **INITIAL** ___/___/___ **REVISED** ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(_ _ _) _ _ _ - _ _ _ _ HICN _____	(_ _ _) _ _ _ - _ _ _ _ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___; Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	HCPCS CODES / REPLACEMENT (*check if applicable*) / WARRANTY (*see reverse*) Length (months) / Type (1-4)

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ **1-99 (99=LIFETIME)** **DIAGNOSIS CODES (ICD-9):** _____ _____ _____ _____

ANSWERS	ANSWER QUESTIONS 1 -5 FOR SEAT LIFT MECHANISM (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply)
Y N D	1. Does the patient have severe arthritis of the hip or knee?
Y N D	2. Does the patient have a severe neuromuscular disease?
Y N D	3. Is the patient completely incapable of standing up from a regular armchair or <u>any</u> chair in his/her home?
Y N D	4. Once standing, does the patient have the ability to ambulate?
Y N D	5. Have all appropriate therapeutic modalities to enable the patient to transfer from a chair to a standing position (e.g., medication, physical therapy) been tried and failed? If YES, this is documented in the patient's medical records.

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	**PHYSICIAN'S UPIN:** _____
	PHYSICIAN'S TELEPHONE #: (_ _ _) _ _ _ - _ _ _ _

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked, "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 07.02A**

Certificate Of Medical Necessity: SEAT LIFT MECHANISM **PAGE 2 OF 2**

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories and options ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, and option.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 07.02B

Certificate Of Medical Necessity: POWER OPERATED VEHICLE (POV) PAGE 1 OF 2

SECTION A **Certification Type/Date:** INITIAL ___/___/___ REVISED ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(___) ___-____ HICN _____	(___) ___-____ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___; Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	

HCPCS CODES	REPLACEMENT (check if applicable)	WARRANTY (see reverse) Length (months)	Type (1-4)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ **1-99 (99=LIFETIME)** **DIAGNOSIS CODES (ICD-9):** _____ _____ _____ _____

ANSWERS	ANSWER QUESTIONS 6 - 14 FOR POWER OPERATED VEHICLE (POV) (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply)
	Questions 1 - 5, and 9 - 11, reserved for other or future use.
Y N D	6. Does the patient require a POV to move around in their residence?
Y N D	7. Have all types of manual wheelchairs (including lightweights) been considered and ruled out?
Y N D	8. Does the patient require a POV only for movement outside their residence?
Y N D	12. Is the physician signing this form a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology?
Y N D	13. Is the patient more than one day's round trip from a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology?
Y N D	14. Does the patient's physical condition prevent a visit to a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology?

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	
	PHYSICIAN'S UPIN: _____
	PHYSICIAN'S TELEPHONE #: (___) ___-____

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked, "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 07.02B**

Certificate Of Medical Necessity: POWER OPERATED VEHICLE (POV) **PAGE 2 OF 2**

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories and options ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, and option.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 08.02**

DMERC Information Form: IMMUNOSUPPRESSIVE DRUGS

ALL INFORMATION ON THIS FORM MAY BE COMPLETED BY THE SUPPLIER

Certification Type/Date: **INITIAL** ___/___/___ **REVISED** ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(___) ___-____ HICN _____	(___) ___-____ NSC # _____
PLACE OF SERVICE _____ NAME and ADDRESS of FACILITY if applicable (see reverse):	PT DOB ___/___/___; Sex ___ (M/F)

TRANSPLANT DIAGNOSIS CODES (ICD-9) (CIRCLE APPROPRIATE CODES): V42.1 (HEART); V42.7 (LIVER); V42 .0 (KIDNEY); V42.6 (LUNG); V42.8 (BONE MARROW); V42.8 (OTHER-SPECIFY) (_____)

ANSWERS	ANSWER QUESTIONS 1 - 5 AND 8 - 12 FOR IMMUNOSUPPRESSIVE DRUGS (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply, Unless Otherwise Noted)
	Questions 6 and 7, reserved for other or future use.
	What are the drug(s) prescribed and the dosage and frequency of administration of each? HCPCS MG TIMES PER DAY 1. _____ _____ _____ 2. _____ _____ _____ 3. _____ _____ _____
Y N	4. Has the patient had an organ transplant that was covered by Medicare?
Enter Correct Number(s) ____ ____ ____	5. Which organ(s) have been transplanted? (List most recent transplant) (May enter up to three different organs). 1 - Heart 2 - Liver 3 - Kidney 4 - Bone Marrow 5 - Lung
_____	8. Name of facility where transplant was performed.
_____	9. City where facility is located.
_____	10. State where facility is located.
___/___/___	11. On what date was the patient discharged from the hospital following this transplant surgery?
Y N	12. Was there a prior transplant failure of this same organ?

PHYSICIAN NAME, ADDRESS (Printed or Typed)	_____ ___/___/___ SUPPLIER'S SIGNATURE DATE (A Stamped Signature Is Not Acceptable)
UPIN: _____ TELEPHONE #: (___) ___-____	_____ PRINT NAME

Rev. 7/25/95

ALL INFORMATION ON THIS FORM MAY BE COMPLETED BY THE SUPPLIER

CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked, "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED."
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the drug is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female).
TRANSPLANT DIAGNOSIS CODES:	Circle the appropriate ICD-9 code reflecting the organ transplant for which this immunosuppressive drug is being prescribed. If an organ other than those listed was transplanted, circle V42.8 and print or type in the name of the organ in the parentheses.
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the drugs ordered, circling "Y" for yes, "N" for no, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.
SUPPLIER'S SIGNATURE:	The person who completed this form and accepts responsibility for the accuracy and completeness of the information contained on this form, signs and dates this form. Signature and date stamps are not acceptable.
PRINTED NAME:	The person signing the form, legibly prints or types his/her name.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** DMERC 09.02

Certificate Of Medical Necessity: EXTERNAL INFUSION PUMP PAGE 1 OF 2

SECTION A **Certification Type/Date:** INITIAL ___/___/___ REVISED ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(_ _ _) _ _ _-_ _ _ _ HICN _____	(_ _ _) _ _ _-_ _ _ _ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___; Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	HCPCS CODES / REPLACEMENT (*check if applicable*) / WARRANTY (*see reverse*) Length (months) / Type (1-4)

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ 1-99 (99=LIFETIME) **DIAGNOSIS CODES (ICD-9): _____ _____ _____ _____**

ANSWERS	ANSWER QUESTIONS 1 - 7 FOR EXTERNAL INFUSION PUMP. (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply, Unless Otherwise Noted)
1 3 4	1. Circle number of pump which has been prescribed: 1 - External infusion pump (non-disposable); 2 - Reserved for other or future use; 3 - Implantable infusion pump; 4 - Disposable infusion pump (e.g., elastomeric)
HCPCS CODE: _____	2. Provide the HCPCS code for the drug that requires the use of the pump.
_____	3. If non-specific code was used to answer questions, print name of drug.
1 3 4	4. Circle number for route of administration? 1 - Intravenous; 2 - Reserved for other or future use; 3 - Epidural; 4 - Subcutaneous
1 2 3	5. Circle number for method of administration? 1 - Continuous; 2 - Intermittent; 3 - Bolus
_____	6. What is the total duration of drug infusion per 24 hours? (1 - 24)
Y N D	7. Does the patient have intractable cancer pain which has failed to respond to an adequate oral/transdermal narcotic analgesic regimen or is the patient unable to tolerate oral/transdermal narcotics?

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	
	PHYSICIAN'S UPIN: _____
	PHYSICIAN'S TELEPHONE #: (_ _ _) _ _ _-_ _ _ _

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked, "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank; if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 09.02**

Certificate Of Medical Necessity: EXTERNAL INFUSION PUMP **PAGE 2 OF 2**

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories, options, supplies and drugs ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, option, supply and drug.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 10.02A**

Certificate Of Medical Necessity: PARENTERAL NUTRITION **PAGE 1 OF 2**

SECTION A **Certification Type/Date:** **INITIAL** ___/___/___ **REVISED** ___/___/___ **RECERTIFICATION** ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(___) ___-____ HICN _____	(___) ___-____ NSC # _____
PLACE OF SERVICE _____	PT DOB ___/___/___; HT _____ (in.); WT. _____ (lbs.); Sex ____ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	HCPCS CODES / REPLACEMENT (*check if applicable*) / WARRANTY (*see reverse*) Length (months) / Type (1-4)

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ **1-99 (99=LIFETIME)** **DIAGNOSIS CODES (ICD-9):** _____ _____ _____ _____

ANSWERS	ANSWER QUESTIONS 1, AND 3 - 5 FOR PARENTERAL NUTRITION (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply, Unless Otherwise Noted)
	Question 2 reserved for other or future use.
Y N	1. Does the patient have severe permanent disease of the gastrointestinal tract causing malabsorption severe enough to prevent maintenance of weight and strength commensurate with the patient's overall health status?
_____	3. Days per week infused? (Enter 1 - 7).
	4. Formula components: Amino Acid _____(ml/day) _____concentration % _____gms protein/day Dextrose _____(ml/day) _____concentration % Lipids _____(ml/day) _____days/week _____concentration %
1 3 7	5. Circle the number for the route of administration. 2, 4, 5, 6 - Reserved for other or future use. 1 - Central Line; 3 - Hemodialysis Access Line; 7 - Peripherally Inserted Catheter (PIC)

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	**PHYSICIAN'S UPIN:** _____ **PHYSICIAN'S TELEPHONE #:** (___) ___-____

Rev. 7/25/95

SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked. "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 10.02A**

Certificate Of Medical Necessity: PARENTERAL NUTRITION **PAGE 2 OF 2**

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories, options and supplies ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, option and supply.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

Rev. 7/25/95

SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 10.02B**

Certificate Of Medical Necessity: ENTERAL NUTRITION **PAGE 1 OF 2**

SECTION A **Certification Type/Date:** **INITIAL** __/__/__ **REVISED** __/__/__ **RECERTIFICATION** __/__/__

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER
(___) ___-____ HICN _____	(___) ___-____ NSC # _____
PLACE OF SERVICE _____	PT DOB __/__/__; HT. _____ (in.); WT. _____ (lbs.); Sex ___ (M/F)
NAME and ADDRESS of FACILITY if applicable (see reverse):	

HCPCS CODES	REPLACEMENT (*check if applicable*)	WARRANTY (*see reverse*) Length (months)	Type (1-4)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

SECTION B **Information Below May Not Be Completed By The Supplier Of The Items/Supplies, Nor Anyone In A Financial Relationship With The Supplier.**

EST. LENGTH OF NEED (# OF MONTHS): _____ **1-99 (99=LIFETIME)** **DIAGNOSIS CODES (ICD-9):** _____ _____ _____ _____

ANSWERS	ANSWER QUESTIONS 7, 8, AND 10 - 15 FOR ENTERAL NUTRITION (Circle **Y** for Yes, **N** for No, or **D** for Does Not Apply, Unless Otherwise Noted)
	Questions 1 - 6, and 9, reserved for other or future use.
Y N	7. Does the patient have permanent non-function or disease of the structures that normally permit food to reach or be absorbed from the small bowel?
Y N	8. Does the patient require tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status?
A) _____ B) _____	10. Print product name(s).
A) _____ B) _____	11. Calories per day for each product?
_____	12. Days per week administered? (Enter 1 - 7)
1 2 3 4	13. Circle the number for method of administration? 1 - Syringe 2 - Gravity 3 - Pump 4 - Does not apply
Y N D	14. Does the patient have a documented allergy or intolerance to semi-synthetic nutrients?
	15. Additional information when required by policy:

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

NAME: _____ TITLE: _____

PHYSICIAN NAME, ADDRESS (Printed or Typed)	
	PHYSICIAN'S UPIN: _____
	PHYSICIAN'S TELEPHONE #: (___) ___-____

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SECTION A:	**(May be completed by the supplier)**
CERTIFICATION TYPE/DATE:	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked, "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked, "INITIAL," and also indicate the effective date of the order change in the space marked, "REVISED." If this is a recertification (to be completed at intervals required by the DMERC), indicate the initial date needed in the space marked, "INITIAL," and also indicate the recertification date in the space marked, "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.
PATIENT INFORMATION:	Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on the his/her Medicare card and on the claim form.
SUPPLIER INFORMATION:	Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).
PLACE OF SERVICE:	Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.
FACILITY NAME:	If the place of service is a facility, indicate the name and complete address of the facility.
PATIENT DOB, HEIGHT, WEIGHT AND SEX:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
HCPCS CODES, WARRANTY:	List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN. If the item billed is a replacement for a previously purchased item, place a check mark in the blank for that HCPCS code. If the item ordered is covered by a warranty, the length and type of warranty must be indicated. If there is more than one warranty on the item, only the longest warranty Length (months or years) should be indicated that applies to any one of the warranty types on that item. List only the one warranty Type that lasts the longest: (1): Full replacement; (2): Pro-rated replacement; (3): Parts & Labor; (4): Parts Only.
SECTION B:	**(May not be completed by the supplier nor anyone in a financial relationship with the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D, Page 2 of this CMN) by the ordering physician.)**
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.
DIAGNOSIS CODES:	In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).
QUESTION SECTION:	This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank, if other information is requested.
ITEM ADDRESSED COLUMN:	(This only appears on certain CMNs.) When it appears, it references the equipment being addressed by each question. It is intended to be educational for the ordering physician.
NAME OF PERSON ANSWERING SECTION B QUESTIONS:	If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, nutritionist), or a physician employee answers the questions of Section B, he/she must print his/her name and give his/her professional title where indicated. If the physician is answering the questions, this space may be left blank.
PHYSICIAN NAME, ADDRESS:	Indicate physician's name and complete mailing address.
UPIN:	Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).
PHYSICIAN'S TELEPHONE NO:	Indicate the telephone number where the physician can be contacted (preferably a number where records would be accessible pertaining to this patient) if more information is needed.

Effective 10/01/95 **DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER** **DMERC 10.02B**

Certificate Of Medical Necessity: ENTERAL NUTRITION **PAGE 2 OF 2**

PATIENT NAME: _____ **HICN:** _____

SECTION C **Confirmation Of Physician Order / Narrative Description Of Equipment And Cost**

(1) Narrative diagnoses given by physician; **(2)** Narrative description of all items, accessories, options and supplies ordered; **(3)** Supplier's charge; and **(4)** Medicare Fee Schedule Allowance for each item, accessory, option and supply.

(See Instructions On Back)

SECTION D **Physician Attestation and Signature/Date**

I, the patient's physician, certify that I have received Sections A, B, and C of this Certificate Of Medical Necessity (including charges for items ordered). I certify the medical necessity of these items for this patient. I have reviewed the answers in Section B of this form. Any statement on my letterhead attached hereto, has been reviewed and signed by me. The foregoing information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE ____/____/____

(SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

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SECTION C:	**(To be completed by the supplier)**
CONFIRMATION OF PHYSICIAN ORDER/ NARRATIVE DESCRIPTION OF EQUIPMENT & COST:	Supplier confirms physician's original order, giving **(1)** narrative diagnoses given by physician; **(2)** a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; **(3)** the supplier's charge for each item, option, accessory, supply and drug; and **(4)** the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.
SECTION D:	**(Physician Attestation and Signature)**
PHYSICIAN ATTESTATION:	The physician's signature certifies that **(1)** the Certificate of Medical Necessity which he/she is reviewing includes two sheets containing Sections A, B, C and D; **(2)** Section B has not been completed by the supplier nor anyone in a financial relationship with the supplier, and the answers are correct; **(3)** the diagnoses and prescribed items listed in Section C are accurate.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies that the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

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To make the reporting deadlines for studies conducted in Federal court demonstration districts consistent with the deadlines for pilot districts, and for other purposes. (Oct. 3, 1995; 109 Stat. 292; 1 page)

S. 532/P.L. 104–34

To clarify the rules governing venue, and for other purposes. (Oct. 3, 1995; 109 Stat. 293; 1 page)

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