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WHEN: Tuesday, February 7, 2006
9:00 a.m.–Noon

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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Contents

Federal Register

Vol. 71, No. 15

Tuesday, January 24, 2006

Advisory Council on Historic Preservation
See Historic Preservation, Advisory Council

Agency for Healthcare Research and Quality
NOTICES
Meetings:
Health Services Research Initial Review Group Committee, 3850–3851
Primary and secondary health; topics nominations, 3849–3850

Agricultural Marketing Service
NOTICES
Fresh asparagus; grade standards, 3815–3816
Globe artichokes; grade standards, 3816
Mixed commodities; grade standards, 3816–3817
Pea pods; grade standards, 3817–3818
Strawberries; grade standards, 3818
Table grapes (European or Vinifera type); grade standards, 3818–3819

Agriculture Department
See Agricultural Marketing Service
See Commodity Credit Corporation
See Food and Nutrition Service
See Forest Service

Air Force Department
NOTICES
Environmental statements; notice of intent:
Nevada Test and Training Range, NV; depleted uranium use increase, 3825–3826

Army Department
See Engineers Corps
NOTICES
Environmental statements; availability, etc.:
Fort Irwin, CA; maneuver training land addition; correction, 3919

Centers for Disease Control and Prevention
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 3851–3852
Energy Employees Occupational Illness Compensation Program Act of 2000:
Special Exposure Cohort; employee class designations—
Linde Ceramics Plant, Tonawanda, NY, 3852

Centers for Medicare & Medicaid Services
NOTICES
Medicaid:
State plan amendments, reconsideration; hearings—
Ohio, 3853–3854

Coast Guard
RULES
Drawbridge operations:
Virginia, 3763–3764
NOTICES
Reports and guidance documents; availability, etc.:
Vessels arriving to United States; entry conditions imposition notification; policy enforcement, 3873–3874
Vessel inspection:
Certificates of inspection and compliance; temporary extension authorization, 3874–3875

Commerce Department
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration
NOTICES
Committees; establishment, renewal, termination, etc.:
Sea Grant Review Panel, 3821

Commodity Credit Corporation
PROPOSED RULES
Export programs:
Supplier Credit Guarantee Program, 3790–3791

Customs and Border Protection Bureau
NOTICES
Automation program test:
Automated Commercial Environment—
Truck carrier accounts; automated truck manifest data; deployment schedule, 3875

Defense Department
See Air Force Department
See Army Department
See Engineers Corps
NOTICES
Federal Acquisition Regulation (FAR):
Agency information collection activities; proposals, submissions, and approvals, 3826

Education Department
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 3826–3829
Grants and cooperative agreements; availability, etc.:
Elementary and secondary education—
Early Reading First Program; correction, 3829
Postsecondary education—
Developing Hispanic-Serving Institutions Program, 3830–3834

Employment and Training Administration
NOTICES
Adjustment assistance; applications, determinations, etc.:
Hewlett Packard et al., 3886–3888
OBG Manufacturing Co., 3888
Plasti-Coil, Inc., 3888–3889
Polyvision Corp., 3889
TexStyle, Inc., 3889

Energy Department
See Federal Energy Regulatory Commission

NOTICES
Environmental statements; record of decision:
Savannah River Site, SC; salt processing alternatives, 3834–3838
Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005; Section 3116 determinations:
Savannah River Site, SC; salt waste disposal, 3838–3839

Engineers Corps
NOTICES
Environmental statements; notice of intent:
Yuba County, CA; Yuba River Basin Project; correction, 3919

Environmental Protection Agency
RULES
Air quality implementation plans; approval and promulgation; various States:
Colorado, 3773–3776
Montana, 3770–3773, 3776–3779
North Dakota, 3764–3768
Oregon, 3768–3770
Solid waste:
State municipal solid waste landfill permit programs—Maine, 3779–3781
PROPOSED RULES
Air quality implementation plans; approval and promulgation; various States:
Colorado, 3796–3797
Montana, 3796
North Dakota, 3795–3796
Solid waste:
State municipal solid waste landfill permit programs—Maine, 3797
NOTICES
Grants and cooperative agreements; availability, etc.:
Conferences, workshops, and/or meetings; planning, arranging, administering, and conducting, 3842–3843
Water pollution control:
Total maximum daily loads—Arkansas, 3843–3844

Executive Office of the President
See Trade Representative, Office of United States

Federal Aviation Administration
RULES
Airworthiness directives:
Airbus, 3757–3759
Turbomeca S.A., 3754–3757
Airworthiness standards:
Special conditions—Airbus Model A380-800 airplane, 3753–3754
Class E airspace, 3759–3762
PROPOSED RULES
Airworthiness directives:
Fokker, 3792–3794
Class E airspace, 3794–3795
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 3915
Environmental statements; availability, etc.:
Las Vegas McCarran International Airport, NV, 3915
Environmental statements; notice of intent:
Upham, NM; commercial launch site development and operation; scoping meetings, 3915–3917
Exemption petitions; summary and disposition, 3917
Meetings:
RTCA, Inc., 3917–3918
Reports and guidance documents; availability, etc.:
Advisory circulars, other policy documents, and proposed technical standard orders; availability on agency website, 3918

Federal Energy Regulatory Commission
NOTICES
Complaints filed:
Tucson Electric Power Co., 3839
Electric rate and corporate regulation combined filings, 3839–3841
Environmental statements; availability, etc.:
Alaska Power & Telephone Co., 3841
Hydroelectric applications, 3841–3842

Federal Maritime Commission
NOTICES
Investigations, hearings, petitions, etc.:
Worldwide Relocations, Inc., et al., 3844

Federal Reserve System
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 3844–3846
Banks and bank holding companies:
Change in bank control, 3846–3847
Formations, acquisitions, and mergers, 3847
Meetings; Sunshine Act, 3847

Fish and Wildlife Service
NOTICES
Comprehensive conservation plans; availability, etc.:
Choctaw National Wildlife Refuge, AL, 3878–3882
Endangered and threatened species:
Survival enhancement permits—Florida red-cockaded woodpecker; safe harbor agreement, 3882–3883

Food and Drug Administration
RULES
Human drugs and biological products:
Prescription drug products; labeling requirements, 3922–3997
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 3854–3860
Reports and guidance documents; availability, etc.:
Labeling for human prescription drug and biological products—
Content and format; clinical studies and adverse reactions sections; industry guidance, 3999–4000
New content and format requirements; warnings and precautions, contraindications, etc.; industry guidance, 3998–3999

Food and Nutrition Service
NOTICES
Child nutrition programs:
Summer Food Service Program—Reimbursement rates, 3819–3820

Forest Service
NOTICES
Meetings:
Resource Advisory Committees—
Lincoln County, 3821
Southwest Mississippi, 3820–3821

Reports and guidance documents; availability, etc.:
National Environmental Policy Act; implementation—
Oil and gas exploration and development activities; documentation; categorical exclusion; correction, 3919

General Services Administration
RULES
Privacy Act; implementation, 3781–3786
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 3847–3848
Federal Acquisition Regulation (FAR):
Agency information collection activities; proposals, submissions, and approvals, 3826

Health and Human Services Department
See Agency for Healthcare Research and Quality
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health
NOTICES
Poverty income guidelines; annual update, 3848–3849

Historic Preservation, Advisory Council
NOTICES
National Historic Preservation Act:
Mount Graham, AZ; microwave communications system replacement, 3815

Homeland Security Department
See Coast Guard
See Customs and Border Protection Bureau
See U.S. Citizenship and Immigration Services
NOTICES
United States Visitor and Immigrant Status Indicator Technology Program (US-VISIT):
Biometrically enabled travel documents; privacy impact assessment, 3873

Housing and Urban Development Department
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 3877–3878

Indian Affairs Bureau
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 3883–3884

Industry and Security Bureau
NOTICES
Meetings:
Transportation and Related Equipment Technical Advisory Committee, 3821–3822

Interior Department
See Fish and Wildlife Service
See Indian Affairs Bureau
See Land Management Bureau
See National Park Service
See Reclamation Bureau

Internal Revenue Service
RULES
Income taxes:
Widely held fixed investment trusts; reporting requirements, 4002–4025

International Trade Administration
NOTICES
Antidumping:
Carbon and alloy steel wire rod from—
Canada, 3822–3824
Uranium from—
Russian Federation, 3824
Welded carbon steel pipe and tube from—
Turkey, 3824–3825

Justice Department
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 3885–3886
Pollution control; consent judgments:
Cascade Cooperage, Inc., 3886

Labor Department
See Employment and Training Administration
See Mine Safety and Health Administration
NOTICES
Organization, functions, and authority delegations:
Emergency Management Center et al., 4028–4030
Government Accountability Office, 4032

Land Management Bureau
NOTICES
Resource management plans, etc.:
Anchorage Field Office-administered lands from Dixon Entrance to Attu Island, AK; Ring of Fire Resource Area, 3884

Mine Safety and Health Administration
NOTICES
Petitions for safety standards modification; summary of affirmative decisions; correction, 3889–3891

National Aeronautics and Space Administration
NOTICES
Federal Acquisition Regulation (FAR):
Agency information collection activities; proposals, submissions, and approvals, 3826

National Archives and Records Administration
NOTICES
Privacy Act; systems of records, 3891–3893

National Highway Traffic Safety Administration
RULES
Motor vehicle safety standards:
Controls, telltales, and indicators; effective date delay, 3786–3789

National Institutes of Health
NOTICES
Meetings:
Fogarty International Center Advisory Board, 3860
National Cancer Institute, 3860–3862
National Center for Research Resources, 3862–3863
National Heart, Lung, and Blood Institute, 3863
National Institute of Allergy and Infectious Diseases, 3866–3867
National Institute of Child Health and Human Development, 3865
National Institute of Dental and Craniofacial Research, 3867
National Institute of Environmental Health Sciences, 3863

National Institute of Mental Health, 3864
National Institute of Neurological Disorders and Stroke, 3864–3865
National Institute on Alcohol Abuse and Alcoholism, 3864
National Institute on Deafness and Other Communication Disorders, 3867–3868
National Institute on Drug Abuse, 3865–3866
National Library of Medicine, 3868
Scientific Review Center, 3868–3873

National Oceanic and Atmospheric Administration
PROPOSED RULES
Fish and seafood promotion:
Species-specific seafood marketing councils, 3797–3814

National Park Service
NOTICES
Meetings:
Route 66 Corridor Preservation Program Advisory Council, 3884–3885

Nuclear Regulatory Commission
PROPOSED RULES
Plants and materials; physical protection:
Design basis threat, 3791–3792
NOTICES
Meetings; Sunshine Act, 3893–3894

Office of United States Trade Representative
See Trade Representative, Office of United States

Postal Rate Commission
NOTICES
Practice and procedure:
Repositionable notes; minor classification changes, 3894–3895

Reclamation Bureau
NOTICES
Environmental statements; availability, etc.:
San Luis Unit of Central Valley Project, CA; long-term contract renewal, 3885

Securities and Exchange Commission
NOTICES
Agency information collection activities; proposals, submission, and approvals, 3895–3896
Joint Industry Plan:
Pacific Exchange, Inc., et al., 3896–3906
Meetings; Sunshine Act, 3906–3907
Privacy Act; systems of records, 3907–3908
Self-regulatory organizations; proposed rule changes:
Chicago Board Options Exchange, Inc., 3908–3909
National Association of Securities Dealers, Inc., 3909–3910
Pacific Exchange, Inc., 3910–3911

Small Business Administration
NOTICES
Disaster loan areas:
Oklahoma, 3911–3912
Puerto Rico, 3912
Texas, 3912

Social Security Administration
NOTICES
Foreign insurance or pension systems:
Japan, 3913

State Department
RULES
International Traffic in Arms regulations:
Registration fee change, 3762–3763
NOTICES
Meetings:
Arms Control and Nonproliferation Advisory Board, 3913–3914
Reports and guidance documents; availability, etc.:
Exchange Visitor Program—
J-1 agriculture training programs; policy statement, 3914
J-1 flight training programs; policy statement, 3913

Trade Representative, Office of United States
NOTICES
Generalized System of Preferences:
Pakistan; intellectual property protection; 2005 annual country practice review; case closure, 3914

Transportation Department
See Federal Aviation Administration
See National Highway Traffic Safety Administration

Treasury Department
See Internal Revenue Service

U.S. Citizenship and Immigration Services
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 3875–3877

Veterans Affairs Department
NOTICES
Meetings:
National Research Advisory Council, 3918

Separate Parts In This Issue

Part II
Health and Human Services Department, Food and Drug Administration, 3922–4000

Part III
Treasury Department, Internal Revenue Service, 4002–4025

Part IV
Labor Department, 4028–4030

Part V
Labor Department, 4032

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

7 CFR

Proposed Rules:

1493 3790

10 CFR

Proposed Rules:

73 3791

14 CFR

25 3753
39 (2 documents) 3754, 3757
71 (3 documents) ... 3759, 3760, 3761

Proposed Rules:

39 3792
71 3794

21 CFR

201 3922
314 3922
601 3922

22 CFR

122 3762
129 3762

26 CFR

1 4002
301 4002
602 4002

33 CFR

117 3763

40 CFR

52 (5 documents) ... 3764, 3768, 3770, 3773, 3776
60 3776
239 3779
257 3779
258 3779

Proposed Rules:

52 (3 documents) 3795, 3796
239 3797
257 3797
258 3797

41 CFR

105 3781

49 CFR

571 3786

50 CFR

Proposed Rules:

270 3797

Rules and Regulations

Federal Register
Vol. 71, No. 15
Tuesday, January 24, 2006

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM316; Special Conditions No. 25–312–SC]

Special Conditions: Airbus Model A380–800 Airplane, Discrete Gust Requirements

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Airbus A380–800 airplane. This airplane will have novel or unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. Many of these novel or unusual design features are associated with the complex systems and the configuration of the airplane, including its full-length double deck. For these design features, the applicable airworthiness regulations do not contain adequate or appropriate safety standards regarding discrete gust requirements. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards. Additional special conditions will be issued for other novel or unusual design features of the Airbus Model A380–800 airplane.

EFFECTIVE DATE: The effective date of these special conditions is January 10, 2006.

FOR FURTHER INFORMATION CONTACT: Holly Thorson, FAA, International Branch, ANM–116, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (425) 227–1357; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Background

Airbus applied for FAA certification/validation of the provisionally-designated Model A3XX–100 in its letter AI/L 810.0223/98, dated August 12, 1998, to the FAA. Application for certification by the Joint Aviation Authorities (JAA) of Europe had been made on January 16, 1998, reference AI/L 810.0019/98. In its letter to the FAA, Airbus requested an extension to the 5-year period for type certification in accordance with 14 CFR 21.17(c).

The request was for an extension to a 7-year period, using the date of the initial application letter to the JAA as the reference date. The reason given by Airbus for the request for extension is related to the technical challenges, complexity, and the number of new and novel features on the airplane. On November 12, 1998, the Manager, Aircraft Engineering Division, AIR–100, granted Airbus' request for the 7-year period, based on the date of application to the JAA.

In its letter AI/LE–A 828.0040/99 Issue 3, dated July 20, 2001, Airbus stated that its target date for type certification of the Model A380–800 has been moved from May 2005, to January 2006, to match the delivery date of the first production airplane. In accordance with 14 CFR 21.17(d)(2), Airbus chose a new application date of April 20, 1999, and requested that the 7-year certification period which had already been approved be continued. The part 25 certification basis for the Model A380–800 airplane was adjusted to reflect the new application date.

The Model A380–800 airplane will be an all-new, four-engine jet transport airplane with a full double-deck, two-aisle cabin. The maximum takeoff weight will be 1.235 million pounds with a typical three-class layout of 555 passengers.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Airbus must show that the Model A380–800 airplane meets the applicable provisions of 14 CFR part 25, as amended by Amendments 25–1 through 25–98. If the Administrator finds that the applicable airworthiness regulations do not contain adequate or appropriate safety standards for the Airbus A380–800 airplane because of novel or unusual design features, special conditions are prescribed under the provisions of 14 CFR 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Airbus Model A380–800 airplane must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36. In addition, the FAA must issue a finding of regulatory adequacy pursuant to section 611 of Public Law 93–574, the ''Noise Control Act of 1972.''

Special conditions, as defined in 14 CFR 11.19, are issued in accordance with 14 CFR 11.38 and become part of the type certification basis in accordance with 14 CFR 21.17(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of 14 CFR 21.101.

Discussion of Novel or Unusual Design Features

In terms of requirements pertaining to discrete gusts, the size of the Airbus Model A380 is a novel or unusual design feature. These requirements are found in 14 CFR 25.341 (Amendment 25–86) which specifies that the gust loads acting on the airplane are to be determined by dynamic analysis, considering the dynamic and rigid body responses of the airplane. Section 25.341(a)(3) requires that a sufficient number of gust gradient distances in the range of 30 feet to 350 feet be investigated to find the critical response for each load quantity. For large airplanes, the longer gust gradient distances are vital to assess the rigid body response.

At the time § 25.341 was adopted, the value of the upper end of the range of gust gradient distances to be investigated was determined from the largest commercial airplane then in existence, the Boeing Model 747. This value was calculated to be the mean geometric chord of the Boeing 747 (which is 28 feet) multiplied by 12.5, which equals 350 feet.

Since the mean geometric chord of the A380 is larger than that of the Boeing 747, a special condition is necessary to define an appropriate upper value for the range of gust gradient distances to be investigated. That value would be the mean geometric chord of the A380 (which is 34.8 feet) multiplied by 12.5, which equals 435 feet. Increasing the range of gust gradient distances to be investigated to 435 feet will ensure an appropriate analysis of the critical rigid body response of the A380.

Discussion of Comments

Notice of Proposed Special Conditions No. 25–05–11–C, pertaining to discrete gust requirements for the Airbus A380 airplane, was published in the **Federal Register** on August 9, 2005 (70 FR 46113). A single comment was received which supports the intent and the language of the special condition, as proposed.

Applicability

As discussed above, these special conditions are applicable to the Airbus A380–800 airplane. Should Airbus apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design features, these special conditions would apply to that model as well under the provisions of § 21.101.

Conclusion

This action affects only certain novel or unusual design features of the Airbus A380–800 airplane. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration (FAA), the following special conditions are issued as part of the type certification basis for the Airbus A380–800 airplane.

In lieu of the requirements of § 25.341(a)(3), the following special conditions apply:

A sufficient number of gust gradient distances in the range of 30 feet to 435 feet (12.5 times the Geometric Chord of the Model A380) must be investigated to find the critical response for each load quantity.

Issued in Renton, Washington, on January 10, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–598 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–21242; Directorate Identifier 2005–NE–09–AD; Amendment 39–14460; AD 2006–02–08]

RIN 2120–AA64

Airworthiness Directives; Turbomeca Arriel 1B, 1D, 1D1, and 1S1 Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Turbomeca Arriel 1B, 1D, 1D1, and 1S1 turboshaft engines. This AD requires initial and repetitive position checks of the gas generator 2nd stage turbine blades on all Turbomeca Arriel 1B, 1D, 1D1, and 1S1 turboshaft engines, and initial and repetitive replacements of 2nd stage turbines on 1B, 1D, and 1D1 engines only. This AD results from reports of the release of gas generator 2nd stage turbine blades while in service, with full containment of debris. We are issuing this AD to prevent inflight engine shutdown and subsequent forced autorotation landing or accident.

DATES: This AD becomes effective February 28, 2006. The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of February 28, 2006.

We must receive any comments on this AD by March 27, 2006.

ADDRESSES: Use one of the following addresses to comment on this AD:

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Turbomeca, 40220 Tarnos, France; telephone +33 05 59 74 40 00, fax +33 05 59 74 45 15, for the service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Christopher Spinney, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7175, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with a proposed airworthiness directive (AD). The proposed AD applies to Turbomeca Arriel 1B engines fitted with 2nd stage turbine modification TU 148, and Arriel 1D, 1D1, and 1S1 engines. We published the proposed AD in the **Federal Register** on June 28, 2005 (70 FR 37063). That action proposed to require initial and repetitive position checks of the 2nd stage turbine blades on Turbomeca Arriel 1B, 1D, 1D1, and 1S1 turboshaft engines, and replacement of 2nd stage turbines on 1B and 1D1 engines only.

Examining the AD Docket

You may examine the docket that contains the AD, any comments received, and any final disposition in person at the Docket Management Facility Docket Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone (800) 647–5227) is located on the plaza level of the Department of Transportation Nassif Building at the street address stated in **ADDRESSES.** Comments will be available in the AD docket shortly after the DMS receives them.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments received.

Request To Change the Compliance Time

One commenter, Turbomeca, requests we change the compliance time for replacing 2nd stage turbines to, immediately upon receipt of a replacement 2nd stage turbine from Turbomeca, and at least by August 31, 2006. The commenter states that without this requirement, operators will incur unacceptable and unnecessary risk for engines operating past the

hourly life limit. The commenter further states that an unacceptable number of engines will require replacement 2nd stage turbines at the compliance end-date, causing grounding of aircraft because of a lack of replacement parts. We partially agree. There is a need to replace the 2nd stage turbines as they reach the hourly life limit, and to strive to not allow them to stay installed until the compliance end-date. However, replacing them immediately upon receipt could unnecessarily create compliance problems for operators. An example would be if a helicopter is at a remote site the day an operator receives a replacement 2nd stage turbine. We changed the compliance to read ''After accumulating 1,500 hours TSN or TSO for Arriel 1D and 1D1 engines, and 2,200 hours TSN or TSO for Arriel 1B engines, initially replace the 2nd stage turbine with a new or overhauled 2nd stage turbine as soon as practicable, but no later than August 31, 2006.'' This change prevents compliance problems associated with the commenter's phrase ''immediately upon receipt'' yet still requires prompt replacement of 2nd stage turbines after one becomes available.

NPRM Not Clear About Ongoing Requirement

The same commenter states that the NPRM is not clear that replacing the 2nd stage turbines is an ongoing requirement. We agree. We changed the compliance in this AD to address initial and repetitive replacements of 2nd stage turbines.

Inspection and Replacement Requirements Changed for Arriel 1D Turboshaft Engines

The same commenter states that the requirements for inspecting and replacing Arriel 1D turboshaft engines have changed since we issued the NPRM. Those requirements are now the same as for Arriel 1D1 turboshaft engines. We agree. We changed the compliance in this AD to shorten the repetitive inspection interval and add the requirement to replace the 2nd stage turbine. However, since many of the Arriel 1D turboshaft engines may be at or near the compliance time for replacing the 2nd stage turbine, we have found that notice and opportunity for further comment before issuing this AD, are impracticable. We are issuing this AD as a final rule; request for comments, allowing operators to comment after the AD publishes.

Conclusion

We have carefully reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Interim Action

These actions are interim actions and we may take further rulemaking actions in the future.

Costs of Compliance

There are about 2,557 Turbomeca Arriel 1B, 1D, 1D1 and 1S1 turboshaft engines of the affected design in the worldwide fleet. We estimate that this AD will affect 721 engines installed on helicopters of U.S. registry. We estimate that it will take about 2 work hours per engine to inspect all 721 engines and 40 hours per engine to replace about 571 2nd stage turbines on 1B and 1D1 engines, and that the average labor rate is $65 per work hour. Required parts will cost about $3,200 per engine. Based on these figures, we estimate the total cost of the AD to U.S. operators to be $3,405,530.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''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) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary at the address listed under **ADDRESSES**.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2006–02–08 Turbomeca: Amendment 39–14460; Docket No. FAA–2005–21242; Directorate Identifier. 2005–NE–09–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective February 28, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Turbomeca Arriel 1B engines fitted with 2nd stage turbine modification TU 148, and Arriel 1D, 1D1, and 1S1 engines. Arriel 1B engines are installed on, but not limited to, Eurocopter France AS–350B and AS–350A ''Ecureuil'' helicopters; 1D engines are installed on, but not limited to, Eurocopter France AS–350B1 ''Ecureuil'' helicopters; 1D1 engines are installed on, but not limited to, Eurocopter France AS–350B2 ''Ecureuil'' helicopters; and Arriel 1S1 engines are installed on, but not limited to, Sikorsky Aircraft S–76A and S–76C helicopters.

Unsafe Condition

(d) This AD results from reports of the release of gas generator 2nd stage turbine blades while in service, with full containment of debris. We are issuing this AD to prevent inflight engine shutdown and subsequent forced autorotation landing or accident.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified unless the actions have already been done.

Initial Relative Position Check of 2nd Stage Turbine Blades

(f) Do an initial relative position check of the 2nd stage turbine blades using the Turbomeca mandatory alert service bulletins (ASBs) specified in the following Table 1 before reaching any of the intervals specified in Table 1 or within 50 hours time-in-service after the effective date of this AD, whichever occurs later.

TABLE 1.—INITIAL AND REPETITIVE RELATIVE POSITION CHECK INTERVALS OF 2ND STAGE TURBINE BLADE

Turbomeca engine model	Initial relative position check interval	Repetitive interval	Mandatory alert service bulletin
Arriel 1B (modified per TU 148).	Within 1,200 hours time-since-new (TSN) or time-since-overhaul (TSO) or 3,500 cycles-since-new (CSN) or cycles-since-overhaul (CSO), whichever occurs earlier.	Within 200 hours time-in-service-since-last-relative-position-check (TSLRPC).	A292 72 0807, dated March 24, 2004.
Arriel 1D1 and Arriel 1D.	Within 1,200 hours TSN or TSO or 3,500 hours CSN or CSO, whichever occurs earlier.	Within 150 hours TSLRPC.	A292 72 0809, Update No. 1, dated October 4, 2005.
Arriel 1S1	Within 1,200 hours TSN or TSO or 3,500 hours CSN or CSO, whichever occurs earlier.	Within 150 hours TSLRPC.	A292 72 0810, dated March 24, 2004.

Repetitive Relative Position Check of 2nd Stage Turbine Blades

(g) Recheck the relative position of 2nd stage turbine blades at the TSLRPC intervals specified in Table 1 of this AD, using the mandatory ASBs indicated.

Credit for Previous Relative Position Checks

(h) Relative position checks of 2nd stage turbine blades done using Turbomeca Service Bulletin A292 72 0263, Update 1, 2, 3, or 4, may be used to show compliance with the initial requirements of paragraph (f) of this AD.

Initial Replacement of 2nd Stage Turbines on Arriel 1B, 1D, and 1D1 Engines

(i) After accumulating 1,500 hours TSN or TSO for Arriel 1D and 1D1 engines, and 2,200 hours TSN or TSO for Arriel 1B engines, initially replace the 2nd stage turbine with a new or overhauled 2nd stage turbine as soon as practicable, but no later than August 31, 2006.

Repetitive Replacements of 2nd Stage Turbines on Arriel 1B, 1D, and 1D1 Engines

(j) Thereafter, replace the 2nd stage turbine with a new or overhauled 2nd stage turbine within every 1,500 hours TSN or TSO for Arriel 1D and 1D1 engines, and within every 2,200 hours TSN or TSO for Arriel 1B engines.

Criteria for Overhauled 2nd Stage Turbines

(k) Do the following to overhauled 2nd stage turbines, referenced in paragraphs (i) and (j) of this AD:

(1) You must install new blades in the 2nd stage turbines of overhauled Arriel 1D and 1D1 engines.

(2) You may install either overhauled or new blades in the 2nd stage turbines of overhauled Arriel 1B engines.

Relative Position Check Continuing Compliance Requirements

(l) All 2nd stage turbines, including those that are new or overhauled, must continue to comply with relative position check requirements of paragraphs (f) and (j) of this AD.

Alternative Methods of Compliance

(m) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Related Information

(n) DGAC airworthiness directive F–2004–047 R1, dated October 26, 2005, also addresses the subject of this AD.

Material Incorporated by Reference

(o) You must use the service information specified in Table 2 of this AD to perform the actions required by this AD. The Director of the Federal Register approved the incorporation by reference of the documents listed in Table 2 of this AD in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact Turbomeca, 40220 Tarnos, France; telephone +33 05 59 74 40 00, fax +33 05 59 74 45 15, for a copy of this service information. You may review copies at the Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001, on the Internet at *http://dms.dot.gov*, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

TABLE 2.—INCORPORATION BY REFERENCE

Turbomeca mandatory alert service bulletin No.	Page	Update No.	Date
A292 72 0807 ..... Total Pages: 17	ALL	Original	March 24, 2004.
A292 72 0809 ..... Total Pages: 18	ALL	1	October 4, 2005.
A292 72 0810 ..... Total Pages: 14	ALL	Original	March 24, 2004.

Issued in Burlington, Massachusetts, on January 12, 2006.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 06–522 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–18565; Directorate Identifier 2003–NM–168–AD; Amendment 39–14461; AD 2006–02–09]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330–200, A330–300, A340–200, and A340–300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Model Airbus Model A330–200, A330–300, A340–200, and A340–300 series airplanes. This AD requires inspecting for damage to certain actuators of the low-pressure shut-off valve (LPSOV), and related investigative and corrective actions if necessary. This AD results from a report of damage to the LPSOV pedestal. We are issuing this AD to ensure that, in the event of an engine fire, the LPSOV actuator functions properly to delay or block the fuel flow to the engine and prevent an uncontrollable fire.

DATES: This AD becomes effective February 28, 2006.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of February 28, 2006.

ADDRESSES: You may examine the AD docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC.

Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2797; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Examining the Docket

You may examine the airworthiness directive (AD) docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the street address stated in the **ADDRESSES** section.

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to all Airbus Model A330, A340–200, and A340–300 series airplanes; and A340–541 and -642 airplanes. That NPRM was published in the **Federal Register** on July 8, 2004 (69 FR 41211). That NPRM proposed to require inspecting for damage to certain actuators of the low-pressure shut-off valve (LPSOV), and related investigative and corrective actions if necessary.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments received.

Requests To Limit Applicability

One commenter, on behalf of Airbus, requests that we revise the proposed applicability to match that of the French airworthiness directive, which is limited to airplanes equipped with certain LPSOV part numbers (P/Ns). The commenter adds that Model A330–301 airplanes (among others) receive Airbus Modification 48225/48223 in production, and Model A340–541 and –642 airplanes receive Airbus Modification 48552 in production. These modifications involve installing actuator P/N FRH010041.

We infer that the commenter would like us to remove Model A330–301, A340–541, and A340–642 airplanes from the applicability of the proposed AD. Since we issued the proposed AD, French airworthiness directive F–2003–360 R1, dated May 26, 2004, was issued to limit the applicability to A340–200 and –300 series airplanes. We have revised this final rule accordingly. There has been no corresponding revision to French airworthiness directive F–2003–359 to exclude Model A330–301 airplanes.

Another commenter, a Model A330 operator, also requests that we limit the applicability. The commenter reports the following: This operator's entire A330 fleet was delivered with P/N FRH010041 actuators installed, its first A330 was delivered July 2003, and no P/N HTE190021 or P/N HTE190026 actuators have been purchased. Airbus Service Bulletins A330–28–3083 and A340–28–4098, both dated March 25, 2003, limit their effectivity to airplanes delivered up to May 2003, but the proposed AD would not so limit the applicability. The commenter requests that we revise the applicability of the proposed AD to match that of the service bulletins.

As stated in the preamble to the proposed AD, ''the French airworthiness directives specify that Model A330 and A340 series airplanes are affected if they are equipped with LPSOV actuators having certain part numbers.'' The Airbus service bulletins, which are mandated by the French airworthiness directives, specify that operators first identify the part numbers of the actuators. This AD therefore applies to all Model A330 and A340 series airplanes and requires part number identification. Because the part is interchangeable, this AD further ensures that affected LPSOVs are not installed in the future, as required by paragraph (g) of this AD. However, we agree to revise paragraph (f) of this final rule to also allow an airplane records review to determine the part number of the actuator.

Request To Allow Additional Service Information

The proposed AD would require operators to inspect certain LPSOV actuators, and would prohibit installation of affected actuators on or after the effective date of the AD. One commenter, on behalf of an operator of Model A330 airplanes, notes that Task 28–00–00–200–80 of the A330 Aircraft Maintenance Manual (AMM), task 28–00–00–200–801, revised July 1, 2004, provides new installation procedures for measuring the dowel in each LPSOV location. According to the commenter, the AMM should provide sufficient instructions to meet the parts installation requirement (paragraph (g) of the proposed AD); however, as written, paragraph (g) would prohibit installing an affected actuator unless it has been measured specifically in accordance with Airbus Service Bulletin A330–28–3083. The commenter requests that we revise paragraph (g) to also consider the AMM task acceptable for measuring the dowel during installation of the actuator. The commenter asserts that this change will also prevent the inadvertent installation of an actuator that had not been measured, since actuators that have

been inspected in accordance with Airbus Service Bulletin A330–28–3083 are not so marked or identified. The commenter also requests that we allow actuators previously installed in accordance with the AMM after the revision date that added the new measurement task be given credit for the requirements of paragraph (f) of the proposed AD.

The Accomplishment Instructions in the referenced service bulletins refer to the appropriate AMM sections as additional sources of service information. It is not necessary to cite the specific AMM references in this AD. Furthermore, the service bulletin does not refer to a specific revision level of the AMM. Compliance with any revision of the AMM is acceptable for compliance with the requirements of this AD, as long as the required actions (such as measurement) were done. Paragraph (e) of this AD allows for compliance when the required actions have already been done. We have not changed the final rule regarding these references.

Additional Changes to Proposed AD

Paragraph (f)(1) of the proposed AD stated that no further action would be required for airplanes with LPSOV part number FRH010041. However, the requirements of paragraph (g) remain in effect for all airplanes. We have changed paragraph (f)(1) in this final rule to refer only to the requirements of paragraph (f) for those airplanes.

We have revised the applicability of the proposed AD to identify model designations as published in the most recent type certificate data sheet for the affected models.

We have revised this action to clarify the appropriate procedure for notifying the principal inspector before using any approved AMOC on any airplane to which the AMOC applies.

Conclusion

We have carefully reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection	1	$65	No parts	$65	15	$975

Currently, there are no U.S.-registered Model A340–200 or –300 series airplanes; however, if any are imported and placed on the U.S. Register in the future, the estimated costs in the above table would apply.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''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) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

2006–02–09 Airbus: Amendment 39–14461. Docket No. FAA–2004–18565; Directorate Identifier 2003–NM–168–AD.

Effective Date

(a) This AD becomes effective February 28, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Airbus Model A330–201, –202, –203, –223, –243, –301, –321, –322, –323, –341, –342, and –343 airplanes; and Model A340–211, –212, –213, –311, –312, and –313 airplanes; certificated in any category.

Unsafe Condition

(d) This AD results from a report of damage to the pedestal of the low-pressure shut-off valve (LPSOV). We are issuing this AD to ensure that, in the event of an engine fire, the LPSOV actuator functions properly to delay or block the fuel flow to the engine and prevent an uncontrollable fire.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Part Number Identification

(f) At the applicable time specified in Table 1 of this AD, identify the part number (P/N) of the LPSOV actuator. A review of airplane maintenance records is acceptable in lieu of this inspection if the P/N is conclusively determined from that review.

TABLE 1.—COMPLIANCE TIMES

For model—	Do the actions specified in paragraph (f) of this AD at the earlier of the following times:
A330–201, –202, –203, –223, –243, –301, –321, –322, –323, –341, –342, and –343 airplanes.	Within 16,000 flight hours after the effective date of this AD; or Within 53 months after the effective date of this AD.
A340–211, –212, –213, –311, –312, and –313 airplanes	Within 12,000 flight hours after the effective date of this AD; or Within 39 months after the effective date of this AD.

(1) For P/N FRH010041: No further action is required by this paragraph.

(2) For P/N HTE190021 or HTE190026: Before further flight, do a detailed inspection for damage to the LPSOV pedestal, and measure the distance between the face of the mounting flange and the top of the locating pin (dowel). Do the actions in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–28–3083 or A340–28–4098, both dated March 25, 2003, as applicable. Do all related investigative and corrective actions before further flight in accordance with the service bulletin, as applicable.

Note 1: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Note 2: Airbus Service Bulletins A330–28–3083 and A340–28–4098 refer to FR–HiTEMP Service Bulletin HTE190021–28–2, dated March 17, 2003, as an additional source of service information for measuring the flange-to-pin distance.

Parts Installation

(g) As of the effective date of this AD: No person may install an actuator P/N HTE190021 or HTE190026 on any airplane unless the actuator has been measured, and all applicable related investigative and corrective actions have been done, in accordance with the requirements of paragraph (f)(2) of this AD.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with 14 CFR 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(i) French airworthiness directives 2003–359(B), dated October 1, 2003, and F–2003–360 R1, dated May 26, 2004, also address the subject of this AD.

Material Incorporated by Reference

(j) You must use Airbus Service Bulletin A330–28–3083, dated March 25, 2003; or Airbus Service Bulletin A340–28–4098, dated March 25, 2003; as applicable, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC; on the Internet at *http://dms.dot.gov*; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on January 9, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–559 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2005–22856; Airspace Docket No. 05–AAL–36]

Establishment of Class E Airspace; Toksook Bay, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action creates Class E airspace at Toksook Bay, AK to provide adequate controlled airspace to contain aircraft executing a new Standard Instrument Approach Procedure (SIAP) at the airport. This rule results in new Class E airspace upward from 700 ft. and 1,200 ft. above the surface at the Toksook Bay Airport, Toksook Bay AK.

EFFECTIVE DATE: 0901 UTC, April 13, 2006.

FOR FURTHER INFORMATION CONTACT: Gary Rolf, AAL–538G, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; fax: (907) 271–2850; e-mail: *gary.ctr.rolf@faa.gov.* Internet address: *http://www.alaska.faa.gov/at.*

SUPPLEMENTARY INFORMATION:

History

On Thursday, November 17, 2005, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify Class E airspace upward from 700 ft. and 1,200 ft. above the surface at Toksook Bay, AK (70 FR 69709). The action was proposed in order to create Class E airspace sufficient in size to contain aircraft while executing one new SIAP for the Toksook Bay Airport. The new approach is the Area Navigation (Global Positioning System) (RNAV (GPS)) Runway (RWY) 34, original. Class E controlled airspace extending upward from 700 ft. and 1,200 ft. above the surface in the Toksook Bay Airport area is created by this action. Airspace more than 12 Nautical Miles (NM) from the shoreline will be excluded from this action. That controlled airspace outside 12 NM from the shoreline within 35 NM of the geographic point located at 60°21′17″ North latitude, 165°04′01″ West longitude will be created in coordination with HQ FAA ATA–400 by modifying existing Offshore Airspace Areas in accordance with FAA Order 7400.2. That NPRM is currently published as Docket # FAA–2005–22024, 05–AAL–38. The NPRM originally listed the airfield coordinates

differently than this final rule. There has been a subsequent airfield survey conducted since the NPRM was published, which has revised these coordinates. Those listed in the rule below are correct. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No public comments have been received; thus the rule is adopted as proposed.

The area will be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1,200 ft. transition areas are published in paragraph 6005 of FAA Order 7400.9N, *Airspace Designations and Reporting Points,* dated September 1, 2005, and effective September 15, 2005, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 creates Class E airspace at Toksook Bay, Alaska. This Class E airspace is created to accommodate aircraft executing one new SIAP and will be depicted on aeronautical charts for pilot reference. The intended effect of this rule is to provide adequate controlled airspace for Instrument Flight Rule (IFR) operations at Toksook Bay Airport, Toksook Bay, Alaska.

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. It, therefore—(1) is not a ''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 is 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.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart 1, Section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it creates Class E airspace sufficient in size to contain aircraft executing the instrument procedure for the Toksook Bay Airport and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

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—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 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.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9N, *Airspace Designations and Reporting Points*, dated September 1, 2005, and effective September 15, 2005, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Toksook Bay, AK [New]

Toksook Bay Airport, AK

(Lat. 60°32′29″ N., long. 165°05′14″ W.)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Toksook Bay Airport and that airspace extending upward from 1,200 feet above the surface within a 35-mile radius of lat. 60°21′17″ N., long. 165°04′01″ W., excluding that airspace more than 12 miles from the shoreline.

* * * * *

Issued in Anchorage, AK, on January 13, 2006.

Anthony M. Wylie,

Manager, Safety, Area Flight Service Operations.

[FR Doc. 06–601 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2005–22111; Airspace Docket No. 05–AAL–14]

Revision of Class E Airspace; Koyuk Alfred Adams, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace at Koyuk, AK to provide adequate controlled airspace to contain aircraft executing one new Standard Instrument Approach Procedure (SIAP) and two new SIAPs. This rule results in revised Class E airspace upward from 1,200 ft. above the surface at the Koyuk Alfred Adams Airport, Koyuk, AK.

EFFECTIVE DATE: 0901 UTC, April 13, 2006.

FOR FURTHER INFORMATION CONTACT: Gary Rolf, AAL–538G, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; fax: (907) 271–2850; e-mail: *gary.ctr.rolf@faa.gov.* Internet address: *http://www.alaska.faa.gov/at.*

SUPPLEMENTARY INFORMATION:

History

On Thursday, November 17, 2005, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify Class E airspace upward from 1,200 ft. above the surface at Koyuk, AK (70 FR 69713). The action was proposed in order to create Class E airspace sufficient in size to contain aircraft while executing one new and two revised SIAPs for the Koyuk Airport. The new approach is the Area Navigation (Global Positioning System) (RNAV (GPS)) Runway (RWY) 01, original. The two revised approaches are: (1) Non Directional Beacon (NDB) Distance Measuring Equipment (DME) RWY 01, amendment 1, (2) NDB RWY 01, amendment 1. Class E controlled airspace extending upward from 1,200 ft. above the surface in the Koyuk Airport area is modified by this action. Additionally, one small area of Class G

airspace surrounded by Class E airspace is being converted to Class E airspace. The airspace is thus simplified in this area, reducing possible confusion. The NPRM also simply listed this action taking place at Koyuk Airport. The more correct designation is Koyuk Alfred Adams and updates in this rule have been made accordingly. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No public comments have been received; thus the rule is adopted as proposed.

The area will be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1,200 ft. transition areas are published in paragraph 6005 of FAA Order 7400.9N, *Airspace Designations and Reporting Points,* dated September 1, 2005, and effective September 15, 2005, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 modifies Class E airspace at Koyuk, Alaska. This Class E airspace is modified to accommodate aircraft executing one new SIAP, and two revised SIAPs and will be depicted on aeronautical charts for pilot reference. The intended effect of this rule is to provide adequate controlled airspace for Instrument Flight Rule (IFR) operations at Koyuk Alfred Adams Airport, Koyuk, Alaska.

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. It, therefore: (1) Is not a ''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.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart 1, section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it creates Class E airspace sufficient in size to contain aircraft executing instrument procedures for the Koyuk Alfred Adams Airport and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

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—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 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.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9N, *Airspace Designations and Reporting Points*, dated September 1, 2005, and effective September 15, 2005, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Koyuk Alfred Adams, AK [Revised]

Koyuk Alfred Adams Airport, AK
(Lat. 64°56′22″ N., long. 161°09′15″ W.)
Koyuk NDB, AK
(Lat. 64°55′55″ N., long. 161°08′52″ W.)
Norton Bay NDB, AK
(Lat. 64°41′46″ N., long. 162°03′47″ W.)

That airspace extending upward from 700 feet above the surface within a 9-mile radius of the Koyuk Airport and 4 miles west and 8 miles east of the Koyuk NDB 210° bearing extending from the 9-mile radius to 17 miles southwest of the airport; and that airspace extending upward from 1,200 feet above the surface within 5 miles west and 11 miles east of the Koyuk NDB 210° bearing extending from the NDB to 30 miles southwest of the NDB and 4.5 miles either side of the line between the Norton Bay NDB and the Koyuk NDB, and the area within 20 miles of the Koyuk Airport extending clockwise from the Koyuk NDB 140° bearing to the 187° bearing, and the area within 25 miles of the Koyuk Airport extending clockwise from the Koyuk NDB 220° bearing to the 230° bearing.

* * * * *

Issued in Anchorage, AK, on January 13, 2006.

Anthony M. Wylie,

Manager, Safety, Area Flight Service Operations.

[FR Doc. 06–600 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2005–22854; Airspace Docket No. 05–AAL–34]

Revision of Class E Airspace; Holy Cross, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace at Holy Cross, AK to provide adequate controlled airspace to contain aircraft executing two new Standard Instrument Approach Procedures (SIAPs) and revised the Departure Procedure (DP). This rule results in revised Class E airspace upward from 700 ft. above the surface at the Holy Cross Airport, Holy Cross AK.

EFFECTIVE DATE: 0901 UTC, April 13, 2006.

FOR FURTHER INFORMATION CONTACT: Gary Rolf, AAL–538G, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; fax: (907) 271–2850; email: *gary.ctr.rolf@faa.gov.* Internet address: *http://www.alaska.faa.gov/at.*

SUPPLEMENTARY INFORMATION:

History

On Thursday, November 17, 2005, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify Class E airspace upward from 700 ft. above the surface at Holy Cross, AK (70 FR 69710). The action was proposed in order to create Class E airspace sufficient in size to contain aircraft while executing two new SIAPs and one revised DP for the Holy Cross Airport. The new

approaches are the Area Navigation (Global Positioning System) (RNAV (GPS)) Runway (RWY) 01, original, (2) RNAV (GPS) RWY 19, original. The unnamed revised DP is published in the front of the U.S. Terminal Procedures Alaska Vol 1. Class E controlled airspace extending upward from 700 ft. above the surface in the Holy Cross Airport area is modified by this action. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No public comments have been received; thus the rule is adopted as proposed.

The area will be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1,200 ft. transition areas are published in paragraph 6005 of FAA Order 7400.9N, *Airspace Designations and Reporting Points,* dated September 1, 2005, and effective September 15, 2005, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 modifies Class E airspace at Holy Cross, Alaska. This Class E airspace is modified to accommodate aircraft executing two new SIAPs, and one revised DP and will be depicted on aeronautical charts for pilot reference. The intended effect of this rule is to provide adequate controlled airspace for Instrument Flight Rule (IFR) operations at Holy Cross Airport, Holy Cross, Alaska.

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. It, therefore—(1) is not a ''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.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart 1, Section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it creates Class E airspace sufficient in size to contain aircraft executing instrument procedures for the Holy Cross Airport and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

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—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 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.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9N, *Airspace Designations and Reporting Points,* dated September 1, 2005, and effective September 15, 2005, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Holy Cross, AK [Revised]

Holy Cross Airport, AK

(Lat. 62°11′18″ N., long. 159°46′30″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Holy Cross Airport.

* * * * *

Issued in Anchorage, AK, on January 13, 2006.

Anthony M. Wylie,

Manager, Safety, Area Flight Service Operations.

[FR Doc. 06–592 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF STATE

22 CFR Parts 122 and 129

[Public Notice: 5278]

RIN 1400–AB97

Rule Title: Amendment to the International Traffic in Arms Regulations: Registration Fee Change

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule makes final the interim rule that amended the International Traffic in Arms Regulations (ITAR) (22 CFR Parts 122 and 129) by increasing the registration fees, changing the registration renewal period, and making other minor administrative changes. Comments received on the interim rule are analyzed in the **SUPPLEMENTARY INFORMATION** section. No changes were made to the interim rule.

DATES: *Effective Date:* The interim rule is adopted as final February 23, 2006.

FOR FURTHER INFORMATION CONTACT: David Trimble, Office of Defense Trade Controls Compliance, Bureau of Political-Military Affairs, Department of State, Washington, DC 20522–0112, 202–663–2807 or FAX 202–261–8199. ATTN: ITAR Regulatory Change, 22 CFR part 122 and part 129.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 2004, the Department of State published an interim rule (Public Notice 4920; 69 FR 70888), with a request for comments, amending the ITAR (22 CFR parts 122 and 129) by increasing the registration fees, changing the registration renewal period, and making other minor administrative changes. The administration of the Arms Export Control Act (22 U.S.C. 2751 *et seq.*), regulations for which are set forth in the ITAR, is a foreign affairs function. The Department received 43 comments from ITAR registrants and defense-related associations.

Comment Analysis

Impact on Small Business and Fee Relief

The majority of comments received concerned the fee increase's impact on small businesses. The comments provided noted the burden the fee increase would place on small businesses, and some sought relief from the increase. Prior to the publication of the interim rule, the Department fully considered the financial burden the fee increase would place on industry and small businesses when it decided upon the new fee structure, and concluded that the impact would be minimal for the majority of the registrants. In addition, as noted in the Regulatory Findings and Notice section, the Department has found that this fee increase will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Rational for Increasing Registration Fees

Ten comments were received regarding the rationale for increasing the registration fee. The Department has increased the ITAR registration fee to help fund the activities of its Directorate of Defense Trade Controls (DDTC), as set forth in 22 U.S.C. 2717. In particular, the additional revenue will assist DDTC in achieving its goals of expanded automation, compliance, training, and quality assurance. The additional resources will enable DDTC to serve the export community with greater efficiency. This increase in registration fees is the first increase since 1997.

Registration Requirements

Three comments were received regarding whether particular entities must register with DDTC. The interim rule and this final rule address an increase in the registration fee, the registration renewal period, and other minor administrative changes. The regulations pertaining to who must register with DDTC remain unchanged. Pursuant to 22 CFR 122.1, any person who engages in the United States in the business of either manufacturing or exporting defense articles or furnishing defense services is required to register with the Office (now Directorate) of Defense Trade Controls. Manufacturers who do not engage in exporting must nevertheless register. In addition, 22 CFR 129.1 states that section 38(b)(1)(A)(ii) of the Arms Export Control Act (22 U.S.C. 2778) provides that persons engaged in the business of brokering activities shall register and pay a registration fee. Furthermore, 22 CFR 129.2 states that, *inter alia,* brokering activities include activities by U.S. persons who are located inside or outside of the United States or foreign persons subject to U.S. jurisdiction involving defense articles or defense services of U.S. or foreign origin, which are located inside or outside of the United States.

Rationale for Two-Year Registration

Two comments were received requesting the retention of the option to register up to a maximum period of four years. DDTC has reduced the maximum registration period to two years because the increased volume of mergers and acquisitions by regulated companies has made it more difficult to maintain accurate information on registrants. Also, DDTC encountered problems with companies not updating their registration, except at the time of their renewal, as required by 22 CFR 129.4(c). The change from a four-year to a two-year maximum registration period will improve the currency and accuracy of the registrants' information, which is critical to all licensing decisions.

List of Subjects

22 CFR Part 122

Arms and munitions, Exports.

22 CFR Part 129

Arms and munitions, Exports, Technical assistance.

Accordingly, for the reasons set forth above, the interim rule published at 69 FR 70888 is adopted as final.

Dated: Decemher 21, 2005.

Robert G. Joseph,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 06–667 Filed 1–23–06; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD05–06–004]

RIN 1625–AA–09

Drawbridge Operation Regulations; Elizabeth River, Eastern Branch, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Berkley Bridge, at mile 0.4, across the Eastern Branch of the Elizabeth River in Norfolk, Virginia. To facilitate electrical repairs, this deviation allows the drawbridge to remain closed-to-navigation from 7 a.m. on February 7, 2006, to 7 a.m. on February 8, 2006 and from 7 a.m. on February 14, 2006, to 7 a.m. on February 15, 2006.

DATES: This deviation is effective from 7 a.m. on February 7, 2006, to 7 a.m. on February 15, 2006.

FOR FURTHER INFORMATION CONTACT: Gary Heyer, Bridge Management Specialist, Fifth Coast Guard District, at (757) 398–6629.

SUPPLEMENTARY INFORMATION: The Berkley Bridge, a lift-type drawbridge, has a vertical clearance in the closed position to vessels of 48 feet, at mean high water.

The bridge owner, the Virginia Department of Transportation, has requested a temporary deviation from the current operating regulation set out in 33 CFR 117.1007, to effect electrical repairs of the draw span.

To facilitate the repairs, the drawbridge will be closed to navigation from 7 a.m. on February 7, 2006, to 7 a.m. on February 8, 2006 and from 7 a.m. on February 14, 2006, to 7 a.m. on February 15, 2006. During these periods, the repairs require immobilizing the operation of the lift span in the closed-to-navigation position. At all other times, the drawbridge will operate in accordance with the current operating regulations outlined in 33 CFR 117.1007.

The Coast Guard has informed the known users of the waterway so that they can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to

normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: January 17, 2006.

Waverly W. Gregory, Jr.,

Chief, Bridge Administration Branch, Fifth Coast Guard District.

[FR Doc. 06–584 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2005–ND–0002; FRL–8011–1]

Clean Air Act Approval and Promulgation of Air Quality Implementation Plan Revision for North Dakota; Revisions to the Air Pollution Control Rules; Delegation of Authority for New Source Performance Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule and delegation of authority.

SUMMARY: EPA is taking direct final action approving certain revisions to the State Implementation Plan (SIP) as submitted by the Governor of North Dakota with a letter dated April 11, 2003. The revisions affect certain portions of air pollution control rules regarding permitting. This action is being taken under section 110 of the Clean Air Act.

EPA is also providing notice that on July 27, 2005, North Dakota was delegated authority to implement and enforce certain New Source Performance Standards, as of January 31, 2004.

DATES: This rule is effective on March 27, 2006 without further notice, unless EPA receives adverse comment by February 23, 2006. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. R08–OAR–2005–ND–0002, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- Agency Web site: *http://docket.epa.gov/rmepub/.* On November 28, 2005, Regional Material in EDOCKET (RME), EPA's electronic public docket and comment system, was replaced by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov.* Therefore, you will be redirected to that site to access the docket EPA–R08–OAR–2005–ND–0002 and submit comments. Follow the on-line instructions for submitting comments.
- E-mail: *long.richard@epa.gov* and *platt.amy@epa.gov.*
- Fax: (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- Mail: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 200, Denver, Colorado 80202–2466.
- Hand Delivery: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 200, Denver, Colorado 80202–2466. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:55 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. R08–OAR–2005–ND–0002. EPA's policy is that all comments received will be included in the public docket without change and may be made available at *http://docket.epa.gov/rmepub/index.jsp,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA's Regional Materials in EDOCKET and Federal regulations.gov Web site are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET online or see the **Federal Register** of May 31, 2002 (67 FR 38102). For additional instructions on submitting comments, go to Section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the Regional Materials in EDOCKET index at *http://docket.epa.gov/rmepub/index.jsp.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in Regional Materials in EDOCKET or in hard copy at the Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, 999 18th Street, Suite 200, Denver, Colorado 80202–2466. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Amy Platt, Environmental Protection Agency, Region 8, (303) 312–6449, *platt.amy@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information
II. Background
III. Revisions in the April 11, 2003 Submittal That Are the Subject of This Document
IV. Delegation of Authority
V. Section 110(l)
VI. Final Action
VII. Statutory and Executive Order Reviews

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *State* or *ND* mean the State of North Dakota, unless the context indicates otherwise.

(v) The initials NDDH mean or refer to the North Dakota Department of Health.

I. General Information

A. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through Regional Materials in EDOCKET, regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

i. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

The Act requires States to follow certain procedures in developing implementation plans and plan revisions for submission to us. Sections 110(a)(2) and 110(l) of the Act provide that each implementation plan must be adopted after reasonable notice and public hearing.

To provide for public comment, the North Dakota Department of Health (NDDH), after providing notice, held a public hearing on April 19, 2002 to address the revisions to the State Implementation Plan (SIP) and Air Pollution Control Rules. Following the public hearing, comment period, and legal review by the North Dakota Attorney General's Office, the North Dakota State Health Council adopted the revisions, which became effective on March 1, 2003. The North Dakota Governor submitted the SIP revisions to us with a letter dated April 11, 2003.

On October 21, 2004, EPA published a notice of final rulemaking for the State of North Dakota (see 69 FR 61762). In that final rulemaking, we approved portions of the SIP revision submitted by the Governor of North Dakota on April 11, 2003. The portions of the SIP revision that we approved affected the North Dakota Air Pollution Control Rules regarding general provisions and emissions of particulate matter and sulfur compounds.

As we discussed in our October 21, 2004 notice of final rulemaking, we were handling separately the revisions in the April 11, 2003 submittal addressing North Dakota Air Pollution Control Rules Section 33–15–01–13, regarding shutdown and malfunction of an installation, certain portions of Chapter 33–15–14, regarding construction and minor source permitting, and certain portions of Chapter 33–15–15, regarding prevention of significant deterioration.

On August 8, 2005, EPA published a direct final rulemaking for the State of North Dakota (see 70 FR 45539). In that final rulemaking, we approved additional portions of the SIP revision submitted by the Governor of North Dakota on April 11, 2003. Those portions of the SIP revision that we approved affected certain section of the North Dakota Air Pollution Control Rules regarding permitting and prevention of significant deterioration of air quality.

III. Revisions in the April 11, 2003 Submittal That Are the Subject of This Document

The revisions in the April 11, 2003 submittal to be addressed in this document pertain to certain portions of the North Dakota Air Pollution Control Rules regarding permitting, which involve sections of the following chapter of the North Dakota Administrative Code (N.D.A.C.): 33–15–14 Designated Air Contaminant Sources, Permit to Construct, Minor Source Permit to Operate, Title V Permit to Operate (certain sections specific to construction and minor source permitting).

A. Chapter 33–15–14, N.D.A.C., Section 33–15–14–02, Permit To Construct

In the Permit to Construct section, 33–15–14–02, subsection 33–15–14–02.19, Amendment of Permits, was revised to clarify how the NDDH can amend a construction permit. Specifically, in the event that a modification would be a ''major modification'' as defined in the State's prevention of significant deterioration (PSD) regulations, then the procedures established in Chapter 33–15–15, N.D.A.C., must be followed.

B. Chapter 33–15–14, N.D.A.C., Section, 33–15–14–03, Minor Source Permit To Operate

Subsection 33–15–14–03.16, Amendment of Permits, was similarly revised to clarify how the NDDH can amend a minor source permit to operate. Specifically, in the event that a modification would be a ''major modification'' as defined in the State's prevention of significant deterioration (PSD) regulations, then the procedures established in Chapter 33–15–15, N.D.A.C., must be followed.

The revisions discussed above are simply clarifying in nature and are approvable.

IV. Delegation of Authority

With a February 10, 2005 submittal, the Governor of North Dakota requested delegation of authority for revisions to the New Source Performance Standards (NSPS), promulgated in Chapter 33–15–12, N.D.A.C. On July 27, 2005, delegation was given with the following letter:

Ref: 8P–AR

Honorable John Hoeven,
Governor of North Dakota State Capitol, 600 E Boulevard Avenue, Bismarck, North Dakota 58505–0001

Re: Delegation of Clean Air Act New Source Performance Standards

Dear Governor Hoeven:

In a February 10, 2005, letter from you and a February 15, 2005, letter from David Glatt, North Dakota Department of Health (NDDH), the State of North Dakota submitted revisions to its Air Pollution Control Rules and requested direct delegation to implement and enforce the Federal New Source Performance Standards (NSPS). Specifically, North Dakota Administrative Code Chapter 33–15–12, Standards of Performance for New Stationary Sources, was revised to update the citation for the incorporated Federal NSPS in 40 CFR Part 60 as those in effect on January 31, 2004, with the exception of subpart Eb, which the State has not adopted.

Subsequent to States adopting NSPS regulations, EPA delegates the authority for the implementation and enforcement of those

NSPS, so long as the State's regulations are equivalent to the Federal regulations. EPA reviewed the pertinent statutes and regulations of the State of North Dakota and determined that they provide an adequate and effective procedure for the implementation and enforcement of the NSPS by the State. Therefore, pursuant to Section 111(c) of the Clean Air Act (Act), as amended, and 40 CFR Part 60, EPA hereby delegates its authority for the implementation and enforcement of the NSPS to the State of North Dakota as follows:

(A) Responsibility for all sources located, or to be located, in the State of North Dakota subject to the standards of performance for new stationary sources promulgated in 40 CFR Part 60. The categories of new stationary sources covered by this delegation are all NSPS subparts in 40 CFR Part 60, as in effect on January 31, 2004, with the exception of subpart Eb, which the State has not adopted. Note this delegation does not include the emission guidelines in subparts Cb, Cc, Cd, Ce, BBBB, and DDDD. These subparts require state plans which are approved under a separate process pursuant to Section 111(d) of the Act.

(B) Not all authorities of NSPS can be delegated to States under Section 111(c) of the Act, as amended. The EPA Administrator retains authority to implement those sections of the NSPS that require: (1) Approving equivalency determinations and alternative test methods, (2) decision making to ensure national consistency, and (3) EPA rulemaking to implement. Therefore, of the NSPS of 40 CFR Part 60 being delegated in this letter, the enclosure lists examples of sections in 40 CFR Part 60 that cannot be delegated to the State of North Dakota. Please note that the enclosed list has been updated since our November 6, 2003, delegation of authority to implement and enforce the NSPS to the State of North Dakota.

(C) The North Dakota Department of Health (NDDH) and EPA will continue a system of communication sufficient to guarantee that each office is always fully informed and current regarding compliance status of the subject sources and interpretation of the regulations.

(D) Enforcement of the NSPS in the State will be the primary responsibility of the NDDH. If the NDDH determines that such enforcement is not feasible and so notifies EPA, or where the NDDH acts in a manner inconsistent with the terms of this delegation, EPA may exercise its concurrent enforcement authority pursuant to section 113 of the Act, as amended, with respect to sources within the State of North Dakota subject to NSPS.

(E) The State of North Dakota will at no time grant a variance or waiver from compliance with NSPS regulations. Should the NDDH grant such a variance or waiver, EPA will consider the source receiving such relief to be in violation of the applicable Federal regulation and initiate enforcement action against the source pursuant to section 113 of the Act. The granting of such relief by the NDDH shall also constitute grounds for revocation of delegation by EPA.

(F) If at anytime there is a conflict between a State regulation and a Federal regulation (40 CFR Part 60), the Federal regulation must be applied if it is more stringent than that of the State. If the State does not have the authority to enforce the more stringent Federal regulation, this portion of the delegation may be revoked.

(G) If the Regional Administrator determines that a State procedure for enforcing or implementing the NSPS is inadequate, or is not being effectively carried out, this delegation may be revoked in whole or part. Any such revocation shall be effective as of the date specified in a Notice of Revocation to the NDDH.

(H) Acceptance of this delegation of presently promulgated NSPS does not commit the State of North Dakota to accept delegation of future standards and requirements. A new request for delegation will be required for any standards not included in the State's requests of February 10, and 15, 2005.

(I) Upon approval of the Regional Administrator of EPA Region 8, the Director of the NDDH may subdelegate his authority to implement and enforce the NSPS to local air pollution control authorities in the State when such authorities have demonstrated that they have equivalent or more stringent programs in force.

(J) The State of North Dakota must require reporting of all excess emissions from any NSPS source in accordance with 40 CFR 60.7(c).

(K) Performance tests shall be scheduled and conducted in accordance with the procedures set forth in 40 CFR Part 60 unless alternate methods or procedures are approved by the EPA Administrator. Although the Administrator retains the exclusive right to approve equivalent and alternate test methods as specified in 40 CFR 60.8(b)(2) and (3), the State may approve minor changes in methodology provided these changes are reported to EPA Region 8. The Administrator also retains the right to change the opacity standard as specified in 40 CFR 60.11(e).

(L) Determinations of applicability such as those specified in 40 CFR 60.5 and 60.6 shall be consistent with those which have already been made by the EPA.

(M) Alternatives to continuous monitoring procedures or reporting requirements, as outlined in 40 CFR 60.13(i), may be approved by the State only if the specific NSPS grants that authority. Otherwise, EPA retains the authority to review and approve such alternatives.

(N) If a source proposes to modify its operation or facility which may cause the source to be subject to NSPS requirements, the State shall notify EPA Region 8 and obtain a determination on the applicability of the NSPS regulations.

(O) Information shall be made available to the public in accordance with 40 CFR 60.9. Any records, reports, or information provided to, or otherwise obtained by, the State in accordance with the provisions of these regulations shall be made available to the designated representatives of EPA upon request.

(P) All reports required pursuant to the delegated NSPS should not be submitted to the EPA Region 8 office, but rather to the NDDH.

(Q) As 40 CFR Part 60 is updated, North Dakota should revise its regulations accordingly and in a timely manner and submit to EPA requests for updates to its delegation of authority.

EPA is approving North Dakota's request for NSPS delegation for all areas within the State except for the following: Lands within the exterior boundaries of the Fort Berthold, Fort Totten, Standing Rock and Turtle Mountain Indian Reservations; and any other areas which are ''Indian Country'' within the meaning of 18 U.S.C. 1151.

Since this delegation is effective immediately, there is no need for the State to notify the EPA of its acceptance. Unless we receive written notice of objections from you within ten days of the date on which you receive this letter, the State of North Dakota will be deemed to accept all the terms of this delegation. EPA will publish an information notice in the **Federal Register** to inform the public of this delegation, in which this letter will appear in its entirety.

If you have any questions on this matter, please contact me or have your staff contact Richard Long, Director of our Air and Radiation Program, at (303) 312–6005.

Sincerely yours,

Robert E. Roberts

Regional Administrator.

Enclosure

cc: David Glatt, NDDH
Terry O'Clair, NDDH

Enclosure to Letter Delegating NSPS in 40 CFR Part 60, Effective Through January 31, 2004, to the State of North Dakota

EXAMPLES OF AUTHORITIES IN 40 CFR PART 60 WHICH CANNOT BE DELEGATED

40 CFR subparts	Section(s)
A	60.8(b)(2) and (b)(3), and those sections throughout the standards that reference 60.8(b)(2) and (b)(3); 60.11(b) and (e); and 60.13(i).
Da	60.45a.
Db	60.44b(f), 60.44b(g) and 60.49b(a)(4).
Dc	60.48c(a)(4).
Ec	60.56c(i), 60.8.
J	60.105(a)(13)(iii) and 60.106(i)(12).

EXAMPLES OF AUTHORITIES IN 40 CFR PART 60 WHICH CANNOT BE DELEGATED—Continued

40 CFR subparts	Section(s)
Ka	60.114a.
Kb	60.111b(f)(4), 60.114b, 60.116b(e)(3)(iii), 60.116b(e)(3)(iv), and 60.116b(f)(2)(iii).
O	60.153(e).
S	60.195(b).
DD	60.302(d)(3).
GG	60.332(a)(3) and 60.335(a).
VV	60.482–1(c)(2) and 60.484.
WW	60.493(b)(2)(i)(A) and 60.496(a)(1).
XX	60.502(e)(6).
AAA	60.531, 60.533, 60.534, 60.535, 60.536(i)(2), 60.537, 60.538(e) and 60.539.
BBB	60.543(c)(2)(ii)(B).
DDD	60.562–2(c).
GGG	60.592(c).
III	60.613(e).
JJJ	60.623.
KKK	60.634.
NNN	60.663(f).
QQQ	60.694.
RRR	60.703(e).
SSS	60.711(a)(16), 60.713(b)(1)(i) and (ii), 60.713(b)(5)(i), 60.713(d), 60.715(a) and 60.716.
TTT	60.723(b)(1), 60.723(b)(2)(i)(C), 60.723(b)(2)(iv), 60.724(e) and 60.725(b).
VVV	60.743(a)(3)(v)(A) and (B), 60.743(e), 60.745(a) and 60.746.
WWW	60.754(a)(5).
CCCC	60.2030(c).

V. Section 110(l)

Section 110(l) of the Clean Air Act states that a SIP revision cannot be approved if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress towards attainment of the National Ambient Air Quality Standards (NAAQS) or any other applicable requirements of the Act. There are no nonattainment areas in North Dakota. The revisions to the permitting provisions were clarifying in nature, will not affect emissions, and will not interfere with requirements of the Act related to administrative or procedural provisions. Therefore, these revisions do not interfere with attainment or maintenance of the NAAQS or other applicable requirements of the Act.

VI. Final Action

We reviewed the adequacy of these certain revisions submitted by the North Dakota Governor with a letter dated April 11, 2003, and find them approvable. In addition, as requested by the North Dakota Governor with his February 10, 2005 submittal, we are providing notice that we granted delegation of authority to North Dakota on July 27, 2005, to implement and enforce the NSPS promulgated in 40 CFR part 60, promulgated as of January 31, 2004 (except subpart Eb, which the State has not adopted). However, the State's NSPS authorities do not include those authorities which cannot be delegated to the states, as defined in 40 CFR part 60.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the ''Proposed Rules'' section of today's **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective March 27, 2006 without further notice unless the Agency receives adverse comments by February 23, 2006. If the EPA receives adverse comments, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

VII. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and

responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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 March 27, 2006. 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)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: December 7, 2005.

Kerrigan G. Clough,

Acting Regional Administrator, Region 8.

■ 40 CFR part 52 is amended to read as follows:

PART 52—[AMENDED]

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

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

Subpart JJ—North Dakota

■ 2. Section 52.1820 is amended by adding paragraph (c)(35) to read as follows:

§ 52.1820 Identification of plan.

* * * * *

(c) * * *

(35) Certain revisions to the North Dakota State Implementation Plan and Air Pollution Control Rules as submitted by the Governor with a letter dated April 11, 2003. The revisions affect portions of North Dakota Administrative Code (N.D.A.C.) regarding construction and minor source permitting.

(i) Incorporation by reference.

(A) Revisions to the North Dakota Air Pollution Control Rules as follows:

(*1*) In Chapter 33–15–14, N.D.A.C., Designated Air Contaminant Sources, Permit to Construct, Minor Source Permit to Operate, Title V Permit to Operate, the sentence in each first paragraph of subsections 33–15–14–02.19 and 33–15–14–03.16 that reads as follows, ''In the event that the modification would be a major modification as defined in chapter 33–15–15, the department shall follow the procedures established in chapter 33–15–15.'' These revisions were effective March 1, 2003.

[FR Doc. 06–629 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Docket No.: EPA–R10–OAR–2005–OR–0001; FRL–8015–3]

Approval and Promulgation of State Implementation Plans: Oregon; Portland Carbon Monoxide Second 10-Year Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes our approval of the State Implementation Plan (SIP) revisions submitted by the Oregon Department of Environmental Quality on January 3, 2005. EPA is approving the State of Oregon's second 10-year carbon monoxide (CO) maintenance plan for the Portland maintenance area. Specifically, EPA is approving the following: Oregon's demonstration that the Portland CO Attainment Area will maintain air quality standards for CO through the year 2017; a revised CO motor vehicle emissions budget for transportation conformity purposes using the MOBILE6.2 emissions model and latest growth and planning assumptions; and revised state implementation plan (SIP) control strategies and contingency measures.

DATES: This final rule is effective on February 23, 2006.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2005–OR–0001. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the EPA, Region 10, Office of Air, Waste and Toxics (AWT–107), 1200 Sixth Avenue, Seattle WA. EPA requests that if all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30 excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Gina Bonifacino, Office of Air, Waste and Toxics (AWT–107), EPA Region 10,

1200 Sixth Avenue, Seattle WA 98101; telephone number: (206) 553–2970; fax number: (206) 553–0110; e-mail address: *bonifacino.gina@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''awe,'' ''aus,'' or ''aour'' is used, we mean the EPA. Information is organized as follows:

I. What Is the Background of This Rulemaking?
II. What Comments Did We Receive on the Proposed Action?
III. What Is Our Final Action?
IV. Statutory and Executive Order Reviews

I. What Is the Background of This Rulemaking?

On September 6, 2005, EPA published in the **Federal Register,** a detailed description of our proposed action to approve the Portland, Oregon, CO Second 10-year maintenance plan. See 70 FR 52956.

The air quality data shows that the Portland CO maintenance area has not recorded a violation of the primary or secondary CO air quality standards since 1989. EPA believes the area will continue to meet the National Ambient Air Quality Standards (NAAQS or standards) until at least 2017 as required by the Clean Air Act.

II. What Comments Did We Receive on the Proposed Action?

EPA provided a 30-day review and comment period to solicit comments on our proposal published in the September 6, 2005 **Federal Register.** We received one comment letter on the proposed rulemaking. This comment letter was from Pacific Environmental Advocacy Center on behalf of the Northwest Environmental Defense Center. In general, the letter opposed the proposed SIP revision. The comments and our responses are summarized as follows:

Comment: The commenter states that EPA cannot approve Oregon's proposed CO Maintenance Plan because it does not account for agricultural sources' contributions to CO in the Portland area.

Response: The Portland Area Carbon Monoxide Maintenance Plan Emission Inventory and Forecast was prepared using current and applicable EPA procedure and guidance documents and computer software programs. The primary procedure and guidance documents are Procedures for the Preparation of Emission Inventories for Carbon Monoxide and Precursors of Ozone, Volume I, and Emission Inventory Requirements for Carbon Monoxide State Implementation Plans. Emission factors were taken from the supplemental Short List of AMS SCCS and Emission Factors, and Compilation of Air Pollutant Emission Factors (AP–42).

By letter dated November 15, 2005, as corrected on November 21, 2005, the Oregon Department of Environmental Quality (ODEQ) provided specific information in response to the comment. As part of the Portland carbon monoxide maintenance plan, agricultural activity was inventoried per EPA guidance. The types of agricultural activity inventoried by ODEQ were orchard pruning burning (11 tons/year), agriculture field burning (61 tons/year) and non-road agriculture equipment (298.9 tons/year) for a total of 370.8 tons/year. The 370.8 tons of CO that ODEQ calculates are generated by agriculture in the Portland area represents .07% of the region's total. ODEQ informed EPA that there are no Concentrated Animal Feeding Operations (CAFOs) within the boundary of the Portland CO Maintenance Area.

CO is not a pollutant where transport is a concern and there is no information to suggest that CO emissions from CAFOs outside of the Portland CO Maintenance Area impact CO levels within the maintenance area. For these reasons, EPA finds the State of Oregon's second 10-year CO maintenance plan for the Portland CO Maintenance Area adequately accounts for emissions from agricultural sources.

Comment: The commenter states ODEQ cannot properly implement the maintenance plan as a result of budget cuts. Specifically, the commenter is concerned because the ODEQ air program is expected to lose nearly 20 staff members and 4 of the 5 air quality monitors that were installed in the Portland area several years ago are being decommissioned.

Response: ODEQ has informed EPA that the four air quality monitors which are to be decommissioned by ODEQ due to budget cuts are part of a temporary effort to investigate toxic air pollutants in the Portland airshed. The monitors to be removed do not measure CO and are not required by EPA for monitoring of CO. As stated in the maintenance plan submitted by ODEQ, three CO monitors operating in the Portland CO maintenance area will continue to operate throughout the second 10-year period. For these reasons, EPA believes that ODEQ will continue to fulfill the monitoring commitments set forth in the Maintenance Plan.

III. What Is Our Final Action?

EPA is taking final action to approve the Portland, Oregon CO Second 10-Year Maintenance Plan consistent with the published proposal. A Technical Support Document on file at the EPA Region 10 office contains a detailed analysis and rationale in support of the plan.

IV. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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 March 27, 2006. 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).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: December 8, 2005.

L. Michael Bogert,

Regional Administrator, EPA Region 10.

■ 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 *et seq.*

Subpart MM—Oregon

■ 2. Section 52.1970 is amended by adding paragraph (c)(145) to read as follows:

§ 52.1970 Identification of plan.

* * * * *

(c) * * *

(145) On December 27, 2004, the Oregon Department of Environmental Quality submitted to the Regional Administrator of EPA, the Second Portland Area Carbon Monoxide Maintenance Plan that demonstrates continued attainment of the NAAQS for carbon monoxide through the year 2017.

(i) Incorporation by reference.

(A) Oregon Administrative Rules, Chapter 340: 200–0040, 204–0090 and 242–0440, as effective December 15, 2004.

■ 3. Paragraph (a) of § 52.1973 is revised to read as follows:

§ 52.1973 Approval of plans.

(a) Carbon monoxide.

(1) EPA approves as a revision to the Oregon State Implementation Plan, the Second Portland Area Carbon Monoxide Maintenance Plan, effective December 15, 2004, and submitted to EPA on December 27, 2004.

(2) [Reserved]

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[FR Doc. 06–636 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2005–MT–0001, FRL–8012–5]

Approval and Promulgation of Air Quality Implementation Plans; Montana; Revisions to the Administrative Rules of Montana; Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action approving State Implementation Plan (SIP) revisions submitted by the State of Montana on August 25, 2004. The revisions are to the Administrative Rules of Montana and correct internal references to state documents; correct references to, or update citations of, Federal documents; and make minor editorial changes. The intended effect of this action is to make federally enforceable those provisions that EPA is approving. This action is being taken under section 110 of the Clean Air Act.

DATES: This rule is effective on March 27, 2006 without further notice, unless EPA receives adverse comment by February 23, 2006. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2005–MT–0001, by one of the following methods:

- *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- E-mail: *long.richard@epa.gov* and *ostrand.laurie@epa.gov*.
- Fax: (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- Mail: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 200, Denver, Colorado 80202–2466.
- Hand Delivery: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 300, Denver, Colorado 80202–2466. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:55 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2005–MT–0001. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is

an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*. For additional instructions on submitting comments, go to Section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, 999 18th Street, Suite 300, Denver, Colorado 80202–2466. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Laurie Ostrand, Air and Radiation Program, Mailcode 8P–AR, Environmental Protection Agency (EPA), Region 8, 999 18th Street, Suite 200, Denver, Colorado 80202–2466, (303) 312–6437, *ostrand.laurie@epa.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information
II. Background
III. EPA's Review of the State of Montana's August 25, 2004 Submittal
IV. Final Action
V. Statutory and Executive Order Reviews

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA*, *we*, *us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *State* or *Montana* mean the State of Montana, unless the context indicates otherwise.

I. General Information

A. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *http://www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. Background

On August 25, 2004, the Governor submitted a SIP revision that contains amendments to the following sections of the Administrative Rules of Montana (ARM) 17.8.102, 17.8.103, 17.8.106, 17.8.130, 17.8.316, 17.8.320, 17.8.401, 17.8.801, 17.8.819 and 17.8.822. The amendments correct internal references to state documents; correct references to, or update citations of, federal documents; and make minor editorial changes. The Board of Environmental Review adopted the amendments on March 26, 2004.

On December 22, 2004, the Governor of Montana rescinded the submission of the changes to ARM 17.8.102.

III. EPA's Review of the State of Montana's August 25, 2004 Submittal

A. Changes to Sub-Chapter 1—General Provisions

1. Review of changes to ARM 17.8.102—Incorporation by Reference—EPA is not acting on these changes since the Governor rescinded them.

2. Review of changes to ARM 17.8.103—Incorporation by Reference and Availability of Referenced Documents. The state is correcting a reference to the Montana Source Test Protocol and Procedures Manual (July 1994 ed.). We are not acting on these changes at this time.

3. Review of changes to ARM 17.8.106—Source Testing Protocol. The state is correcting a reference to the Montana Source Test Protocol and Procedures Manual (July 1994 ed.). We are not acting on these changes at this time.

4. Review of changes to ARM 17.8.130—Enforcement Procedures—Notice of Violation Order to Take Corrective Action. The state is updating language and making minor editorial changes necessary to conform to the Montana Code Annotated. We are approving all of ARM 17.8.130 as in effect on April 9, 2004.

B. Changes to Sub-Chapter 3—Emission Standards

1. Review of changes to ARM 17.8.316—Incinerators. We are not acting on the changes to ARM 17.8.316 because of other pending changes to this section that we have not acted on yet. We will address both changes in a separate action.

2. Review of changes to ARM 17.8.320(9)—Wood-Waste Burners. The state is correcting internal citations to other state regulations. We are approving ARM 17.8.320(9) as in effect on April 9, 2004.

C. Changes to Sub-Chapter 4—Stack Heights and Dispersion Techniques

1. Review of changes to ARM 17.8.401—Definitions. The state is making minor clerical changes. We are not acting on these changes at this time for the same reasons stated on our August 13, 2001 action (66 FR 42427 at 42434).

D. Changes to Sub-Chapter 8—Prevention of Significant Deterioration of Air Quality

1. Review of changes to ARM 17.8.801—Definitions. The state is making minor clerical changes to how federal documents are cited in the definitions. We are approving the revisions to ARM 17.8.801(22) as in effect on April 9, 2004.

2. Review of changes to ARM 17.8.819—Control Technology Review. The state is making minor clerical changes to how federal documents are cited. We are approving all of ARM 17.8.819 as in effect on April 9, 2004.

3. Review of changes to ARM 17.8.822—Air Quality Analysis. The state is correcting internal citations to other state regulations and making other minor clerical changes. We are approving all of ARM 17.8.822 as in effect on April 9, 2004.

IV. Final Action

EPA is approving the following changes to the ARM that were submitted on August 25, 2004 and effective on April 9, 2004: ARM 17.8.130; 17.8.320(9); 17.8.801(22); 17.8.819; and 17.8.822.

EPA is not acting on the following changes to the ARM that were submitted on August 25, 2004 and effective on April 9, 2004: ARM 17.8.103, 17.8.106, 17.8.316 and 17.8.401. These revisions will be addressed in separate actions.

Section 110(l) of the Clean Air Act states that a SIP revision cannot be approved if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress towards attainment of the NAAQS or any other applicable requirements of the Act. The Montana SIP revisions that are the subject of this document do not interfere with the maintenance of the NAAQS or any other applicable requirement of the Act. The August 25, 2004 submittal merely makes administrative amendments to the State's Administrative Rules of Montana. Therefore, section 110(l) requirements are satisfied.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments; we are merely approving administrative changes to Montana's air rules. However, in the ''Proposed Rules'' section of today's **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective March 27, 2006 without further notice unless the Agency receives adverse comments by February 23, 2006. If the EPA receives adverse comments, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

V. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.**

This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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 March 27, 2006. 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).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: December 7, 2005.

Kerrigan G. Clough,

Acting Regional Administrator, Region 8.

■ 40 CFR part 52 is amended to read as follows:

PART 52—[AMENDED]

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

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

Subpart BB—Montana

■ 2. Section 52.1370 is amended by adding paragraph (c)(62) to read as follows:

§ 52.1370 Identification of plan.

* * * * *

(c) * * *

(62) Revisions to State Implementation Plan were submitted by the State of Montana on August 25, 2004. The revisions correct internal references to state documents; correct references to, or update citations of, Federal documents; and make minor editorial changes.

(i) Incorporation by reference.

(A) Administrative Rules of Montana (ARM) sections: ARM 17.8.130; 17.8.320(9); 17.8.801(22); 17.8.819; and 17.8.822, effective April 9, 2004.

[FR Doc. 06–633 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2005–CO–0002; FRL–8010–2]

Clean Air Act Approval and Promulgation of Air Quality Implementation Plan Revision for Colorado; Long-Term Strategy of State Implementation Plan for Class I Visibility Protection

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action approving a State Implementation Plan (SIP) revision submitted by the Governor of Colorado with a letter dated March 24, 2005. This revision updates the Long-Term Strategy of the Visibility SIP to establish strategies, activities, and monitoring plans that constitute reasonable progress toward the National visibility goal. This action is being taken under section 110 of the Clean Air Act.

DATES: This rule is effective on March 27, 2006 without further notice, unless EPA receives adverse comment by February 23, 2006. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. R08–OAR–2005–CO–0002, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- Agency Web site: *http://docket.epa.gov/rmepub/.* On November 28, 2005, Regional Material in EDOCKET (RME), EPA's electronic public docket and comment system, was replaced by an enhanced Federal-wide electronic docket management and comment system located at *http://www.regulations.gov.* Therefore, you will be redirected to that site to access the docket EPA–R08–OAR–2005–CO–0002 and submit comments. Follow the on-line instructions for submitting comments.
- E-mail: *long.richard@epa.gov* and *platt.amy@epa.gov.*
- Fax: (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- Mail: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 200, Denver, Colorado 80202–2466.
- Hand Delivery: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 200, Denver, Colorado 80202–2466. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:55 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. R08–OAR–2005–CO–0002. EPA's policy is that all comments received will be included in the public docket without change and may be made available at *http://docket.epa.gov/rmepub/index.jsp*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA's Regional Materials in EDOCKET and Federal regulations.gov Web site are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET online or see the **Federal Register** of May 31, 2002 (67 FR 38102). For additional instructions on submitting comments, go to section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the Regional Materials in EDOCKET index at *http://docket.epa.gov/rmepub/index.jsp.* Although listed in the index, some information is not publicly available,

i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in Regional Materials in EDOCKET or in hard copy at the Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, 999 18th Street, Suite 200, Denver, Colorado 80202–2466. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Amy Platt, Environmental Protection Agency, Region 8, (303) 312–6449, *platt.amy@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information
II. Background
III. March 24, 2005 Submittal
IV. Section 110(l)
V. Final Action
VI. Statutory and Executive Order Reviews

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The word *Act* or initials *CAA* mean the Clean Air Act, unless the context indicates otherwise.

(ii) The word *we* or initials *EPA* mean the United States Environmental Protection Agency.

(iii) The initials *SIP* mean State Implementation Plan.

(iv) The word *State* or initials *CO* mean the State of Colorado, unless the context indicates otherwise.

(v) The initials *FLM* mean Federal Land Manager.

I. General Information

A. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through Regional Materials in EDOCKET, regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

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iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

Section 169A of the Clean Air Act (CAA),[1] 42 U.S.C. 7491, establishes as a National goal the prevention of any future, and the remedying of any existing, anthropogenic visibility impairment in mandatory Class I Federal areas[2] (referred to herein as the ''National goal'' or ''National visibility goal''). Section 169A called for EPA to, among other things, issue regulations to assure reasonable progress toward meeting the National visibility goal, including requiring each State with a mandatory Class I Federal area to revise its SIP to contain such emission limits, schedules of compliance and other measures as may be necessary to make reasonable progress toward meeting the National goal (see CAA section 169A(b)(2)). Section 110(a)(2)(J) of the CAA, 42 U.S.C. 7410(a)(2)(J), similarly requires SIPs to meet the visibility protection requirements of the CAA.

We promulgated regulations that required affected States to, among other things, (1) coordinate development of SIPs with appropriate FLMs; (2) develop a program to assess and remedy visibility impairment from new and existing sources; and (3) develop a long-term (10–15 years) strategy to assure reasonable progress toward the National visibility goal. See 45 FR 80084, December 2, 1980 (codified at 40 CFR 51.300–51.307). The regulations provide for the remedying of visibility impairment that is reasonably attributable to a single existing stationary facility or small group of existing stationary facilities. These regulations require that the SIPs provide for periodic review, and revision as appropriate, of the Long-Term Strategy not less frequently than every three years, that the review process include consultation with the appropriate FLMs, and that the State provide a report to the public and EPA that includes an assessment of the State's progress toward the National visibility goal. See 40 CFR 51.306(c).

On July 12, 1985 (50 FR 28544) and November 24, 1987 (52 FR 45132), we disapproved the SIPs of states, including Colorado, that failed to comply with the requirements of the provisions of 40 CFR 51.302 (visibility general plan requirements), 51.305 (visibility monitoring), and 51.306 (visibility long-term strategy). We also incorporated corresponding Federal plans and regulations into the SIPs of these states pursuant to section 110(c)(1) of the CAA, 42 U.S.C. 7410(c)(1).

The Governor of Colorado submitted a SIP revision for visibility protection on December 21, 1987, which met the criteria of 40 CFR 51.302, 51.305, and 51.306 for general plan requirements, monitoring strategy, and long-term strategies. We approved this SIP revision in the August 12, 1988 **Federal Register** (53 FR 30428), and this revision replaced the Federal plans and regulations in the Colorado Visibility SIP. The Governor of Colorado submitted a subsequent SIP revision for visibility protection with a letter dated November 18, 1992, which we approved on October 11, 1994 (59 FR 51376).

After Colorado's 1992 Long-Term Strategy review, the U.S. Forest Service (USFS) certified visibility impairment at Mt. Zirkel Wilderness Area (MZWA) and named the Hayden and Craig generating stations in the Yampa Valley

[1] The Clean Air Act is codified, as amended, in the U.S. Code at 42 U.S.C. 7401, *et seq.*

[2] Mandatory class I Federal areas include international parks, national wilderness areas, and national memorial parks greater than five thousand acres in size, and national parks greater than six thousand acres in size, as described in section 162(a) of the Act (42 U.S.C. 7472(a)). Each mandatory Class I Federal area is the responsibility of a ''Federal land manager'' (FLM), the Secretary of the department with authority over such lands. See section 302(i) of the Act, 42 U.S.C. 7602(i).

of Northwest Colorado as suspected sources. The USFS is the FLM for MZWA. This certification was issued on July 14, 1993. Emissions from the Hayden Station were addressed in the State's August 23, 1996 Long-Term Strategy review and revision (see 62 FR 2305, January 16, 1997). Emissions from the Craig Generating Station were addressed in the State's April 19, 2001 Long-Term Strategy review and revision (see 66 FR 35374, July 5, 2001).

The State conducted its next complete periodic review and revision of the long-term strategy in 2002. With an April 12, 2004, letter, the Governor of Colorado submitted that revision to the Long-Term Strategy of Colorado's SIP for Class I Visibility Protection, which we approved on August 1, 2005 (70 FR 44052).

III. March 24, 2005 Submittal

With a March 24, 2005 letter, the Governor of Colorado submitted a revision to the Long-Term Strategy of Colorado's SIP for Class I Visibility Protection, contained in Part II of the November 18, 2004 document entitled ''Long-Term Strategy Review and Revision of Colorado's State Implementation Plan for Class I Visibility Protection.'' This revision was made to fulfill the requirements to periodically review and, as appropriate, revise the Long-Term Strategy.

The CAA requires States to observe certain procedural requirements in developing implementation plans and plan revisions for submission to EPA. Section 110(a)(2) of the CAA provides that each implementation plan submitted by a State must be adopted after reasonable notice and public hearing. Section 110(l) of the CAA similarly provides that each revision to an implementation plan submitted by a State under the CAA must be adopted by such State after reasonable notice and public hearing.

After providing adequate notice, the Colorado Air Quality Control Commission (AQCC) held a public hearing on November 18, 2004 to consider the proposed revision to the Long-Term Strategy of the Colorado Visibility SIP and adopted the revision. We have reviewed the SIP revision and have determined that it adequately demonstrates that the State is making reasonable progress toward the National visibility goal.

The SIP revision is contained in Part II of the November 18, 2004 document entitled ''Long-Term Strategy Review and Revision of Colorado's State Implementation Plan for Class I Visibility Protection.'' Part II, ''Revision of the Long-Term Strategy,'' incorporates by reference requirements for the Hayden and Craig Generating Stations, including emissions limits and schedules of compliance, as previously approved by EPA on January 16, 1997 (see 62 FR 2305) and July 5, 2001 (see 66 FR 35374). Part II also contains provisions that are explanatory and analyses that are required by section 169A of the CAA, Federal visibility regulations (40 CFR 51.300 to 51.307), and/or the Colorado Visibility SIP. These requirements address existing impairment, ongoing air pollution programs, smoke management practices, prevention of future impairment, and FLM consultation and communication. These revisions are consistent with Federal requirements and demonstrate reasonable further progress toward the National visibility goal as required by 40 CFR 51.306. Therefore, they are approvable.

In addition, Appendix B of Part II of the November 18, 2004 document entitled ''Long-Term Strategy Review and Revision of Colorado's State Implementation Plan for Class I Visibility Protection,'' contains an update of section XIV, Visibility, of Part D of the Colorado Air Quality Control Commission Regulation No. 3 (Stationary Source Permitting and Air Pollutant Emission Notice Requirements). Although this section has not changed substantively since it was last incorporated into the Visibility SIP (*see* 53 FR 30431, August 12, 1988, and 59 FR 51379, October 11, 1994), it has been recodified. Therefore, for clarification purposes, we are also approving this recodified version of the State's visibility regulations in order to update the version incorporated into the Visibility SIP.

V. Section 110(l)

Section 110(l) of the Clean Air Act states that a SIP revision cannot be approved if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress towards attainment of the National Ambient Air Quality Standards (NAAQS) or any other applicable requirements of the Act. The Colorado SIP revisions that are the subject of this document are consistent with Federal requirements and rules. These revisions were made to demonstrate reasonable further progress toward the National visibility goal, as required by the Act. They do not interfere with the attainment or maintenance of the NAAQS or other applicable requirements of the Act.

VI. Final Action

We have reviewed the adequacy of the State's revision to the Long-Term Strategy of Colorado's SIP for Class I Visibility Protection, contained in Part II of the November 18, 2004 document entitled ''Long-Term Strategy Review and Revision of Colorado's State Implementation Plan for Class I Visibility Protection,'' as submitted by the Governor with a letter dated March 24, 2005. We are approving the revision as demonstrating reasonable further progress toward the National visibility goal as required by 40 CFR 51.306.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the ''Proposed Rules'' section of today's **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective March 27, 2006 without further notice unless the Agency receives adverse comments by February 23, 2006. If the EPA receives adverse comments, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

VII. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility

Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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 March 27, 2006. 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).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: December 7, 2005.

Kerrigan G. Clough,

Acting Regional Administrator, Region 8.

■ 40 CFR part 52 is amended to read as follows:

PART 52—[AMENDED]

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

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

Subpart G—Colorado

■ 2. Section 52.320 is amended by adding paragraph (c)(108) to read as follows:

§ 52.320 Identification of plan.

* * * * *

(c) * * *

(108) Revisions to the Long-Term Strategy of Colorado's State Implementation Plan for Class I Visibility Protection (Visibility SIP), as submitted by the Governor on March 24, 2005. The revisions update strategies, activities, and monitoring plans that constitute reasonable progress toward the National visibility goal.

(i) Incorporation by reference.

(A) ''Revision of the Long-Term Strategy'', Part II of the November 18, 2004 document entitled ''Long-Term Strategy Review and Revision of Colorado's State Implementation Plan for Class I Visibility Protection,'' effective November 18, 2004.

(B) Colorado Air Quality Control Commission Regulation No. 3, ''Stationary Source Permitting and Air Pollutant Emission Notice Requirements'', 5 CCR 1001–5, Part D, Section XIV, Visibility, Subsections A through F, effective April 16, 2004.

[FR Doc. 06–630 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 60

[EPA–R08–OAR–2004–MT–0001, FRL–8012–9]

Approval and Promulgation of Air Quality Implementation Plans; Montana; Revisions to the Administrative Rules of Montana; New Source Performance Standards for Montana; Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving State Implementation Plan (SIP) revisions submitted by the State of Montana on August 20, 2003, except for revisions to three rules that EPA will act on at a later date. The revisions modify definitions and references to federal regulations and other materials in the Administrative Rules of Montana. The intended effect of this action is to make federally enforceable those provisions that EPA is approving. This action is being taken under section 110 of the Clean Air Act.

EFFECTIVE DATE: This final rule is effective February 23, 2006.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2004–MT–0001. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through

http://www.regulations.gov or in hard copy at the Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, 999 18th Street, Suite 300, Denver, Colorado 80202–2466. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Laurie Ostrand, Air and Radiation Program, Mailcode 8P–AR, Environmental Protection Agency (EPA), Region 8, 999 18th Street, Suite 200, Denver, Colorado 80202–2466, (303) 312–6437, *ostrand.laurie@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
II. Final Action
III. Statutory and Executive Order Reviews

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *State* or *Montana* mean the State of Montana, unless the context indicates otherwise.

I. Background

On July 20, 2004 (69 FR 43371), EPA published a notice of proposed rulemaking partially approving and partially disapproving SIP revisions submitted by the State of Montana on April 18, 2003 and August 20, 2003. The revisions modify the open burning rules, definitions and references to federal regulations and other materials in the Administrative Rules of Montana. At this time we are finalizing our proposed action on the August 20, 2003 submittal. We will address the April 18, 2003 submittal, pertaining to open burning rules and ARM 17.8.302(1)(f), in a separate action. In the July 20, 2004 proposed rulemaking notice we also announced that on January 9, 2004, pursuant to section 111(c) of the Act, we delegated the authority to the State of Montana to implement and enforce the New Source Performance Standards (NSPS).

The August 20, 2003 submittal contains amendments to definitions and incorporation by reference of current federal regulations and other material into air quality rules at ARM 17.8.101, 17.8.102, 17.8.103, 17.8.106, 17.8.110, 17.8.302, 17.8.401, 17.8.402, 17.8.801, 17.8.802, 17.8.818, 17.8.819, 17.8.821, 17.8.901, 17.8.902, 17.8.905, and 17.8.1002. The amendments update federal citations, make clerical amendments, and eliminate the duplication of statutory language in definitions by citing to the definitions in the statute.

We proposed to approve all of the August 20, 2003 submittal, except for changes in ARM 17.8.401 and 402. In our proposal we indicated that we were not acting on the changes to ARM 17.8.401 and 402 at this time for the same reasons stated on our August 13, 2001 action (66 FR 42427 at 42434). We did not receive any comments on our proposed action of the August 20, 2003 submittal.

We have also decided to not act on the changes to ARM 17.8.106 at this time. We will address ARM 17.8.106 at a later date.

II. Final Action

EPA is approving the following changes to the ARM that were submitted on August 20, 2003 and effective on April 11, 2003: ARM 17.8.101(2), (8), (9), (12), (19), (20), (22), (23), (30) and (36); 17.8.102; 17.8.103(1); 17.8.110(2); 17.8.302(1); 17.8.801(1), (3), (4), (6), (20), (21), (22), (24), (27) and (28); 17.8.802(1); 17.8.818(2), (3) and (6); 17.8.819(3); 17.8.821; 17.8.901(1), (11), (12) and (14); 17.8.902(1); 17.8.905(1)(c); and 17.8.1002(1). We are also approving the deletion of ARM 17.8.101(43) that references definitions in the Montana Code Annotated.

EPA is not acting on the following changes to the ARM that were submitted on August 20, 2003 and effective on April 11, 2003: ARM 17.8.106, 17.8.401 and 17.8.402. These revisions will be addressed in a separate action.

EPA is updating the table in 40 CFR 60.4(c), entitled ''Delegation Status of New Source Performance Standards [(NSPS) for Region VIII],'' to indicate the current status of the 40 CFR part 60 NSPS that are delegated to the State of Montana.

Section 110(l) of the Clean Air Act states that a SIP revision cannot be approved if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress towards attainment of the NAAQS or any other applicable requirements of the Act. The Montana SIP revisions that are the subject of this document do not interfere with the maintenance of the NAAQS or any other applicable requirement of the Act. The August 20, 2003 submittal merely makes administrative amendments to the State's Administrative Rules of Montana. Therefore, section 110(l) requirements are satisfied.

III. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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 March 27, 2006. 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).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 60

Administrative practice and procedure, Air pollution control, Aluminum, Ammonium sulfate plants, Beverages, Carbon monoxide, Cement industry, Coal, Copper, Dry cleaners, Electric power plants, Fertilizers, Fluoride, Gasoline, Glass and glass products, Graphic arts industry, Household appliances, Insulation, Intergovernmental relations, Iron, Lead, Lime, Metallic and nonmetallic mineral processing plants, Metals, Motor vehicles, Natural gas, Nitric acid plants, Nitrogen dioxide, Paper and paper products industry, Particulate matter, Paving and roofing materials, Petroleum, Phosphate, Plastics materials and synthetics, Reporting and recordkeeping requirements, Sewage disposal, Steel, Sulfur oxides, Tires, Urethane, Vinyl, Waste treatment and disposal, Zinc.

Dated: December 7, 2005.

Kerrigan G. Clough,

Acting Regional Administrator, Region 8.

■ 40 CFR parts 52 and 60 are amended to read as follows:

PART 52—[AMENDED]

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

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

Subpart BB—Montana

■ 2. Section 52.1370 is amended by adding paragraph (c)(61) to read as follows:

§ 52.1370 Identification of plan.

* * * * *

(c) * * *

(61) Revisions to State Implementation Plan were submitted by the State of Montana on August 20, 2003. The revisions modify definitions and references to federal regulations and other materials in the Administrative Rules of Montana (ARM). The revisions also delete the definition at ARM 17.8.101(43).

(i) Incorporation by reference.

(A) Administrative Rules of Montana (ARM) sections: ARM 17.8.101(2), (8), (9), (12), (19), (20), (22), (23), (30), and (36); 17.8.102; 17.8.103(1); 17.8.110(2); 17.8.302(1); 17.8.801(1), (3), (4), (6), (20), (21), (22), (24), (27) and (28); 17.8.802(1); 17.8.818(2), (3) and (6); 17.8.819(3); 17.8.821; 17.8.901(1), (11), (12) and (14); 17.8.902(1); 17.8.905(1)(c); and 17.8.1002(1) effective April 11, 2003.

PART 60—[AMENDED]

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401, 7411, 7414, 7416, and 7601 as amended by the Clean Air Act Amendments of 1990, Pub. L. 101–549, 104 Stat. 2399 (November 15, 1990; 402, 409, 415 of the Clean Air Act as amended, 104 Stat. 2399, unless otherwise noted).

Subpart A—General Provisions

■ 2. Section 60.4 is amended by revising the entries for ''Eb—Large Municipal Waste Combustors'' and ''Ec—Hospital/Medical/Infectious Waste Incinerators'' in the table in paragraph (c) entitled ''Delegation Status of New Source Performance Standards [(NSPS) for Region VIII]'' to read as follows:

§ 60.4 Address.

* * * * *

(c) * * *

DELEGATION STATUS OF NEW SOURCE PERFORMANCE STANDARDS

[(NSPS) for Region VIII]

Subpart	CO	MT	ND	SD	UT	WY
* * * *	*		*		*	
Eb—Large Municipal Waste Combustors	.....	X	.....	X	X	X
Ec—Hospital/Medical/Infectious Waste Incinerators	X	X	X	X	X	X
* * * *	*		*		*	

* * * * *

[FR Doc. 06–634 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 239, 257, and 258

[FRL–8024–2]

Maine: Determination of Adequacy for the State Municipal Solid Waste Landfill Permit Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve the State of Maine's permit program for municipal solid waste landfills (MSWLFs) and to approve the State's approach of not allowing conditionally exempt small quantity generator (CESQG) hazardous waste to be sent to non-municipal, non-hazardous waste disposal units. Under the Resource Conservation Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments (HSWA), States may develop and implement permit programs for MSWLFs and for non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste, and submit them for review and an adequacy determination by EPA. Today's approval documents EPA's determination that Maine's MSWLF permit program, and the manner in which the State addresses CESQG hazardous waste with respect to non-municipal, non-hazardous waste disposal units, are adequate to ensure compliance with federal requirements.

DATES: This rule is effective on March 27, 2006 without further notice, unless EPA receives adverse comment by February 23, 2006. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments (including requests for a public hearing) by one of the following methods:

1. Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
2. E-mail: Chuck Franks at: *franks.chuck@epa.gov.*
3. Mail: Chuck Franks, EPA New England—Region 1, One Congress Street, Suite 1100, (Mail Code: CHW), Boston, MA 02114–2023.
4. Hand Delivery or Courier: Deliver your comments to Chuck Franks, EPA New England—Region 1, One Congress Street, Suite 1100, (CHW), Boston, MA 02114–2023.

Instructions: We must receive your comments by February 23, 2006. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov, or e-mail. The Federal regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

You can view and copy Maine's application and associated publicly available materials at the following locations: (1) Maine Department of Environmental Protection (ME DEP), State House Station 17, Hospital Street, Augusta, Maine 04333, business hours: Monday through Thursday, 8:30 a.m. to 4:30 p.m. and Friday, 8:30 a.m. to 12:30 p.m.; interested persons wanting to examine documents at the state office should make an appointment with the ME DEP, Bureau of Remediation and Waste Management at least one day in advance by calling (207) 287–2651; and (2) EPA New England—Region 1 Library, One Congress Street—11th Floor, Boston, MA 02114–2023, business hours: 10 a.m. to 3 p.m., Monday through Thursday, telephone number: (617) 918–1990.

FOR FURTHER INFORMATION CONTACT: Chuck Franks, EPA New England—Region 1, One Congress Street, Suite 1100 (CHW), Boston, MA 02114–2023; telephone number: (617) 918–1554, e-mail: *franks.chuck@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On October 9, 1991, the Environmental Protection Agency (EPA) promulgated the ''Solid Waste Disposal Facility Criteria: Final Rule'' (56 FR 50978). This rule promulgates part 258 of Title 40 of the Code of Federal Regulations (CFR) (40 CFR part 258) which establishes the minimum criteria for Municipal Solid Waste Landfills (MSWLF's). The criteria set out in 40 CFR part 258 include location restrictions and standards for design, operation, groundwater monitoring, corrective action, financial assurance and closure and post-closure care for MSWLFs. On July 1, 1996, EPA amended part 257 of Title 40 of the CFR (40 CFR part 257) by adding Subpart B, ''Federal Disposal Standards for the Receipt of CESQG Wastes at Non-Municipal, Non-Hazardous Waste Disposal Units'' (61 FR 34252). The 40 CFR part 257 criteria include location restrictions and groundwater monitoring and corrective action standards for non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste. Today's rule refers to the 40 CFR part 257, subpart B criteria and the 40 CFR part 258 criteria together as the ''Subtitle D federal revised criteria.'' The Subtitle D federal revised criteria establish minimum federal standards that take into account the practical capability of owners and operators of MSWLFs and non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste while ensuring that these two types of facilities are designed and managed in a manner that is protective of human health and the environment.

Section 4005(c)(1)(B) of Subtitle D of the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984, requires States to develop and implement permit programs to ensure that MSWLFs and non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste will comply with the Subtitle D federal revised criteria. RCRA Section 4005(c)(1)(C) requires EPA to determine whether the permit programs that states develop and implement for these two types of facilities are adequate.

To fulfill this determination requirement, EPA promulgated the State Implementation Rule (SIR). The SIR, which established part 239 of Title 40 of the CFR (40 CFR part 239), has the following four purposes: (1) It spells out the requirements that State programs must satisfy to be determined adequate; (2) it confirms the process for EPA approval or partial approval of State permit programs for MSWLFs and non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste; (3) it provides the procedures for withdrawal of such

approvals; and (4) it establishes a flexible framework for modifications of approved programs.

To receive a determination of adequacy under the SIR, a State must have: (1) Enforceable standards for new and existing MSWLFs and non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste that are technically comparable to the Subtitle D federal revised criteria; (2) authority to issue a permit or other notice of prior approval and conditions to all new and existing MSWLFs and non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste in its jurisdiction; (3) provisions for public participation in permit issuance and enforcement, as required in RCRA Section 7004(b); and (4) sufficient compliance monitoring and enforcement authorities to take specific action against any owner or operator that fails to comply with the state program. EPA expects States to meet all of these requirements for all elements of a permit program before it gives full approval to a State's program.

II. State of Maine

On September 29, 1993, Maine submitted an application for a determination of adequacy of its MSWLF permit program to EPA (Region 1). EPA reviewed the application and requested additional information about program implementation. This information was provided and is part of the application record. Also, as a part of the application process, ME DEP initiated a process to revise portions of Maine's statutes and the Department's solid waste management rules as necessary to make the program consistent with the Federal criteria under 40 CFR part 258.

After EPA provided Maine with initial comments regarding the application, Maine provided EPA with a copy of the proposed draft revisions to their solid waste management rules on August 28, 1995. The August 28, 1995 draft revisions were distributed to an extensive list of potentially interested parties and Maine DEP received public comments concerning this draft which it determined warranted additional draft changes and public review and comment. Subsequent revision drafts dated September 1996 and January 1998 were prepared and distributed for public review and comment and were also forwarded to EPA for agency review relative to the criteria under 40 CFR part 258. The revised MSWLF permit program regulations were adopted by Maine DEP and became effective on November 2, 1998. Subsequent minor revisions to correct errors and omissions or to provide greater clarity to the MSWLF permit program regulations were drafted, distributed for public comment, adopted through formal rulemaking and made effective on September 6, 1999.

On March 22, 2004, the EPA promulgated the Research Development and Demonstration amendments at 40 CFR 258.4. Maine is not seeking approval to implement the provisions of the RD&D amendments in this determination of adequacy. Adopting these provisions is optional. Maine may apply for, and be approved to implement these provisions at a later time.

Based on our review, EPA has determined that Maine's MSWLF permit program meets all of the criteria necessary to qualify for full program approval. The bases for this determination are set forth in checklists comparing the state program to the federal criteria, and other documents, contained in the Administrative Docket.

Maine has not submitted an application for a determination of adequacy under Subtitle D for a permit program for non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste because it does not have such a program. The State instead requires that all hazardous waste disposal, including CESQG hazardous waste disposal, must occur only at hazardous waste disposal facilities that comply with the disposal requirements of RCRA Subtitle C. Therefore, the state exceeds the requirements as set out in 40 CFR part 257, subpart B for non-municipal, non-hazardous waste disposal units receiving CESQG hazardous waste and is, therefore, approved by EPA as having met or exceeded all RCRA Subtitle D CESQG disposal requirements. The State has no plans to revise its current CESQG hazardous waste disposal requirements and has indicated that any potential future changes to Maine's solid waste management rules that may alter these requirements will be forwarded to EPA for approval under the provisions of Subtitle D.

Owners and operators located in States with approved permit programs may benefit from the site-specific flexibility provided by 40 CFR part 257, subpart B, and 40 CFR part 258, to the extent the State program allows such flexibility. States with approved programs may choose to require facilities to comply with the Subtitle D federal revised criteria exactly, or they may choose to allow owners and operators to use site-specific alternative approaches to meet the federal criteria. The flexibility allowed by 40 CFR part 257, subpart B is not applicable in Maine since, as explained above, Maine requires CESQG hazardous waste to be disposed of only at hazardous waste disposal facilities. The Maine regulations generally track the federal regulations and, therefore, generally allow the flexibility provided by 40 CFR part 258.

RCRA Section 4005(a) provides that citizens may use the citizen suit provisions of RCRA Section 7002 to enforce the RCRA Subtitle D Federal revised criteria independent of any State enforcement program. EPA expects that any owner or operator complying with the provisions in a State program approved by EPA should be considered to be in compliance with the criteria set out in 40 CFR part 257, subpart B and 40 CFR part 258.

Maine is not applying at this time for the authority to carry out its federal program in Indian country. Therefore, today's EPA action does not include approval for the State to carry out its program in Indian country within the State, which includes the lands of the Houlton Band of Maliseet Indians, the Aroostook Band of Micmacs, the Passamaquoddy Tribe at Pleasant Point and Indian Township, and the Penobscot Nation. Today's action has no effect on Indian country. EPA will address any issues relating to the State's authority regarding Indian country only if and when the State applies to be authorized to carry out this federal program in Indian country.

III. Public Comments and Public Hearing

The public may submit written comments on this rule. The deadline for submitting written comments is in the **DATES** section of this rule. The mailing and email addresses to which comments should be sent are in the **ADDRESSES** section of this rule. EPA will consider all public comments on this direct final rule that it receives during the public comment period and during any public hearing, if held.

Although RCRA does not require EPA to hold a public hearing on a determination to approve a State's MSWLF permit program and the manner in which CESQG hazardous waste is addressed at non-municipal, non-hazardous waste disposal units, EPA will hold a public hearing on this determination if sufficient public interest is expressed by persons either writing to EPA at the address in the **ADDRESSES** section above or calling the EPA representative listed in the **FOR FURTHER INFORMATION CONTACT** section by February 23, 2006. Should EPA

decide to hold a public hearing, this direct final rule will be revoked and the final deadline for submitting comments will be extended. EPA will notify any persons who submit comments on this notice if there is a public hearing. In addition, anyone who wishes to learn whether the hearing will be held may call the EPA representative listed in the **FOR FURTHER INFORMATION CONTACT** section above.

Copies of Maine's application are available for inspection and copying at the location indicated in the **ADDRESSES** section of this direct final rule.

IV. Regulatory Assessments

The Office of Management and Budget has exempted this type of action from the requirements of Executive Order 12866; therefore, this action is not subject to review by OMB. This action approves State requirements for the purposes of RCRA and imposes no additional requirements beyond those imposed by State law. Accordingly, this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action authorizes pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). For the same reason, and because this action has no effect in Indian country, this action also does not significantly or uniquely affect the communities or Tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves State requirements as part of the State RCRA program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA, EPA grants a State's application as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2) and therefore is not subject to the additional requirements for major rules.

List of Subjects

40 CFR Part 239

Environmental protection, Administrative practice and procedure, Intergovernmental relations, Waste treatment and disposal.

40 CFR Part 257

Waste treatment and disposal.

40 CFR Part 258

Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

Authority: This action is issued under the authority of the Solid Waste Disposal Act as amended 42 U.S.C. 6912, 6945, 6949(a).

Dated: December 27, 2005.

Robert Varney,

Regional Administrator, New England.

[FR Doc. 06–627 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

41 CFR Part 105

[GSPMR Amendment 2006–01; GSPMR Case 2006–105–1]

General Services Administration Property Management Regulations; GSA Privacy Act Rules

AGENCY: Office of the Chief People Officer, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is revising its Privacy Act rules to reflect organizational changes and to update policies and procedures. This revision informs individuals of procedures for obtaining personal information in GSA's systems of records and provides current organizational titles and addresses of offices to contact about the GSA Privacy Program and the systems of records that are maintained by GSA.

DATES: Effective January 24, 2006.

FOR FURTHER INFORMATION CONTACT: GSA Privacy Act Officer, General Services Administration, Office of the Chief People Officer, 1800 F Street NW, Washington DC 20405; telephone (202) 501–1452; or e-mail at *gsa.privacyact@gsa.gov*.

ADDRESSES: GSA Privacy Act Officer (CIB), General Services Administration, 1800 F Street NW, Washington, DC 20405.

SUPPLEMENTARY INFORMATION:

A. Background

GSA undertook a project that focused on making sure that all GSA Privacy Act Rules are still relevant, necessary, and covered by a legal or regulatory authority and that the GSA regulations implementing the Privacy Act Rules reflect the current GSA organization, policies, standards, and practices. As a result of this review GSA is publishing updated Privacy Act Rules. Nothing in the final rule indicates a change in authorities or practices regarding the collection and maintenance of information. The changes do not impact individuals' rights to access or amend their records in the systems of records.

B. Executive Order 12866

This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this final rule. It is not expected to have a significant economic impact on small business entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the rule imposes no record keeping or information collection requirements nor the collection of information from offerors, contractors, or members of the public that would require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*; and the rule is exempt from Congressional review under 5 U.S.C. 801.

List of Subjects in 41 CFR Part 105–64

Privacy.

Dated: January 11, 2006.

June V. Huber,

Director,Office of Information Management,Office of the Chief People Officer.

■ Therefore, GSA is revising 41 CFR part 105–64 as follows:

PART 105–64—GSA PRIVACY ACT RULES

Sec.

105–64.000 What is the purpose of this part?
105–64.001 What terms are defined in this part?

Subpart 105–64.1—Policies and Responsibilities

105–64.101 Who is responsible for enforcing these rules?
105–64.102 What is GSA's policy on disclosure of information in a system of records?
105–64.103 What is GSA's policy on collecting and using information in a system of records?
105–64.104 What must the system manager tell me when soliciting information for a system of records?
105–64.105 When may Social Security Numbers (SSNs) be collected?
105–64.106 What is GSA's policy on information accuracy in a system of records?
105–64.107 What standards of conduct apply to employees with privacy-related responsibilities?
105–64.108 How does GSA safeguard personal information?
105–64.109 How does GSA handle other agencies' records?
105–64.110 When may GSA establish computer matching programs?
105–64.111 What is GSA's policy on directives that may conflict with these rules?

Subpart 105–64.2—Access to Records

105–64.201 How do I get access to my records?
105–64.202 How do I request access in person?
105–64.203 How do I request access in writing?
105–64.204 Can parents and guardians obtain access to records?
105–64.205 Who will provide access to my records?
105–64.206 How long will it take to get my record?
105–64.207 Are there any fees?
105–64.208 What special conditions apply to release of medical records?
105–64.209 What special conditions apply to accessing law enforcement and security records?

Subpart 105–64.3—Denial of Access to Records

105–64.301 Under what conditions will I be denied access to a record?
105–64.302 How will I be denied access?
105–64.303 How do I appeal a denial to access a record?
105–64.304 How are administrative appeal decisions made?
105–64.305 What is my recourse to an appeal denial?

Subpart 105–64.4—Amending Records

105–64.401 Can I amend my records?
105–64.402 What records are not subject to amendment?
105–64.403 What happens when I submit a request to amend a record?
105–64.404 How do I agree to an alternative amendment?
105–64.405 Can I appeal a denial to amend a record?
105–64.406 How will my appeal be handled?
105–64.407 How do I file a Statement of Disagreement?
105–64.408 What is my recourse to a denial decision?

Subpart 105–64.5—Disclosure of Records

105–64.501 Under what conditions may a record be disclosed without my consent?
105–64.502 How do I find out if my record has been disclosed?
105–64.503 What is an accounting of disclosures?
105–64.504 Under what conditions will I be denied an accounting of disclosures?

Subpart 105–64.6—Establishing or Revising Systems of Records in GSA

105–64.601 Procedures for establishing system of records.

Subpart 105–64.7—Assistance and Referrals

105–64.701 Submittal of requests for assistance and referrals.

Appendix A to Part 105–64—Addresses for Geographically Dispersed Records

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

§ 105–64.000 What is the purpose of this part?

This part implements the General Services Administration (GSA) rules under the Privacy Act of 1974, 5 U.S.C. 552a, as amended. The rules cover the GSA systems of records from which information is retrieved by an individual's name or personal identifier. These rules set forth GSA's policies and procedures for accessing, reviewing, amending, and disclosing records covered by the Privacy Act.

§ 105–64.001 What terms are defined in this part?

GSA defines the following terms to ensure consistency of use and understanding of their meaning under this part:

Agency means any organization covered by the Privacy Act as defined in 5 U.S.C. 551(1) and 5 U.S.C. 552a (a)(1). GSA is such an agency.

Individual means a citizen of the United States or a legal resident alien on whom GSA maintains Privacy Act records. An individual may be addressed as *you* when information is provided for the individual's use.

System of records means a group of records from which information is retrieved by the name of an individual, or by any number, symbol, or other identifier assigned to that individual.

Record means any item, collection, or grouping of information about an individual within a system of records which contains the individual's name or any other personal identifier such as number or symbol, fingerprint, voiceprint, or photograph. The information may relate to education, financial transactions, medical conditions, employment, or criminal history collected in connection with an individual's interaction with GSA.

Request for access means a request by an individual to obtain or review his or her record or information in the record.

Disclosure of information means providing a record or the information in a record to someone other than the individual of record.

Exempt records means records exempted from access by an individual under the Privacy Act, subsections (j)(1), Central Intelligence Agency, (j)(2) and (k)(2), law enforcement, (k)(1), Section 552 (b)(1), (k)(3), protective services to the President, (k)(4), statistical records, (k)(5), employee background investigations, (k)(6), federal service disclosure, and (k)(7), promotion in armed services.

Solicitation means a request by an officer or employee of GSA for an individual to provide information about himself or herself for a specified purpose.

Routine use means disclosure of a record outside GSA for the purpose for

which it is intended, as specified in the systems of records notices.

Computer matching program means the computerized comparison of two or more Federal personnel or payroll systems of records, or systems of records used to establish or verify an individual's eligibility for Federal benefits or to recoup delinquent debts.

System manager means the GSA associate responsible for a system of records and the information in it, as noted in the **Federal Register** systems of records notices.

Subpart 105–64.1—Policies and Responsibilities

§ 105–64.101 Who is responsible for enforcing these rules?

GSA Heads of Services and Staff Offices and Regional Administrators are responsible for ensuring that all systems of records under their jurisdiction meet the provisions of the Privacy Act and these rules. System managers are responsible for the system(s) of records assigned to them. The GSA Privacy Act Officer oversees the GSA Privacy Program and establishes privacy-related policy and procedures for the agency under the direction of the GSA Senior Agency Official for Privacy.

§ 105–64.102 What is GSA's policy on disclosure of information in a system of records?

No information contained in a Privacy Act system of records will be disclosed to third parties without the written consent of you, the individual of record, except under the conditions cited in § 105–64.501.

§ 105–64.103 What is GSA's policy on collecting and using information in a system of records?

System managers must collect information that is used to determine your rights, benefits, or privileges under GSA programs directly from you whenever practical, and use the information only for the intended purpose(s).

§ 105–64.104 What must the system manager tell me when soliciting personal information?

When soliciting information from you or a third party for a system of records, system managers must: cite the authority for collecting the information; say whether providing the information is mandatory or voluntary; give the purpose for which the information will be used; state the routine uses of the information; and describe the effect on you, if any, of not providing the information. Any information solicitation forms will contain this information.

§ 105–64.105 When may Social Security Numbers (SSNs) be collected?

Statutory or regulatory authority must exist for collecting Social Security Numbers for record systems that use the SSNs as a method of identification. Systems without statutory or regulatory authority implemented after January 1, 1975, will not collect Social Security Numbers.

§ 105–64.106 What is GSA's policy on information accuracy in a system of records?

System managers will ensure that all Privacy Act records are accurate, relevant, necessary, timely, and complete.

§ 105–64.107 What standards of conduct apply to employees with privacy-related responsibilities?

Employees who design, develop, operate, or maintain Privacy Act record systems will protect system security, avoid unauthorized disclosure of information, both verbal and written, and ensure that no system of records is maintained without public notice. All such employees will follow the standards of conduct in 5 CFR part 2635, 5 CFR part 6701, 5 CFR part 735, and 5 CFR part 2634 to protect personal information.

§ 105–64.108 How is personal information safeguarded?

System managers will establish administrative, technical, and physical safeguards to ensure the security and confidentiality of records, protect the records against possible threats or hazards, and permit access only to authorized persons. Automated systems will incorporate security controls such as password protection, verification of identity of authorized users, detection of break-in attempts, firewalls, or encryption, as appropriate.

§ 105–64.109 How does GSA handle other agencies' records?

In cases where GSA has either permanent or temporary custody of other agencies' records, system managers will coordinate with those agencies on any release of information. Office of Personnel Management (OPM) records that are in GSA's custody are subject to OPM's Privacy Act rules.

§ 105–64.110 When may GSA establish computer matching programs?

System managers will establish computer matching programs or agreements for sharing information with other agencies only with the consent and under the direction of the GSA Data Integrity Board that will be established when and if computer matching programs are used at GSA.

§ 105–64.111 What is GSA's policy on directives that may conflict with these rules?

These rules take precedence over any GSA directive that may conflict with the requirements stated here. GSA officials will ensure that no such conflict exists in new or existing directives.

Subpart 105–64.2—Access to Records

§ 105–64.201 How do I get access to my records?

You may request access to your record in person or by writing to the system manager or, in the case of geographically dispersed records, to the office maintaining the records (see Appendix A). Parents or guardians may obtain access to records of minors or when a court has determined that the individual of record is incompetent.

§ 105–64.202 How do I request access in person?

If appearing in person, you must properly identify yourself through photographic identification such as an agency identification badge, passport, or driver's license. Records will be available during normal business hours at the offices where the records are maintained. You may examine the record and be provided a copy on request. If you want someone else to accompany you when reviewing a record, you must first sign a statement authorizing the disclosure of the record; the statement will be maintained with your record.

§ 105–64.203 How do I request access in writing?

If you request access in writing, mark both the envelope and the request letter ''Privacy Act Request.'' Include in the request your full name and address; a description of the records you seek; the title and number of the system of records as published in the **Federal Register**; a brief description of the nature, time, and place of your association with GSA; and any other information you believe will help in locating the record.

§ 105–64.204 How do parents or guardians obtain access to records?

If you are the parent or guardian of a minor, or of a person judicially determined to be incompetent, you must provide full information about the individual of record. You also must properly identify yourself and provide a copy of the birth certificate of the individual, or a court order establishing guardianship, whichever applies.

§ 105–64.205 Who will provide access to my record?

The system manager will make a record available to you on request, unless special conditions apply, such as for medical, law enforcement, and security records.

§ 105–64.206 How long will it take to get my record?

The system manager will make a record available within 10 workdays after receipt of your request. If a delay of more than 10 workdays is expected, the system manager will notify you in writing of the reason for the delay and when the record will be available. The system manager may ask you for additional information to clarify your request. The system manager will have an additional 10 workdays after receipt of the new information to provide the record to you, or provide another acknowledgment letter if a delay in locating the record is expected.

§ 105–64.207 Are there any fees?

No fees are charged for records when the total fee is less than $25. The system manager may waive the fee above this amount if providing records without charge is customary or in the public interest. When the cost exceeds $25, the fee for a paper copy is 10 cents per page, and the fee for materials other than paper copies is the actual cost of reproduction. For fees above $250, advance payment is required. You should pay by check or money order made payable to the General Services Administration, and provide it to the system manager.

§ 105–64.208 What special conditions apply to release of medical records?

Medical records containing information that may have an adverse effect upon a person will be released only to a physician designated in writing by you, or by your guardian or conservator. Medical records in an Official Personnel Folder (OPF) fall under the jurisdiction of the Office of Personnel Management (OPM) and will be referred to OPM for a response.

§ 105–64.209 What special conditions apply to access of law enforcement and security records?

Law enforcement and security records are generally exempt from disclosure to individuals except when the system manager, in consultation with legal counsel and the Head of the Service or Staff Office or Regional Administrator or their representatives, determines that information in a record has been used or is being used to deny you any right, privilege, or benefit for which you are eligible or entitled under Federal law. If so, the system manager will notify you of the existence of the record and disclose the information, but only to the extent that the information does not identify a confidential source. If disclosure of information could reasonably be expected to identify a confidential source, the record will not be disclosed to you unless it is possible to delete all such information. A confidential source is a person or persons who furnished information during Federal investigations with the understanding that his or her identity would remain confidential.

Subpart 105–64.3—Denial of Access to Records

§ 105–64.301 Under what conditions will I be denied access to a record?

The system manager will deny access to a record that is being compiled in the reasonable anticipation of a civil action or proceeding or to records that are specifically exempted from disclosure by GSA in its system of records notices, published in the **Federal Register**. Exempted systems include the Investigation Case Files, Internal Evaluation Case Files, and Security Files. These systems are exempted to maintain the effectiveness and integrity of investigations conducted by the Office of Inspector General, and others, as part of their duties and responsibilities involving Federal employment, contracts, and security.

§ 105–64.302 How will I be denied access?

If you request access to a record in an exempt system of records, the system manager will consult with the Head of Service or Staff Office or Regional Administrator or their representatives, legal counsel, and other officials as appropriate, to determine if all or part of the record may be disclosed. If the decision is to deny access, the system manager will provide a written notice to you giving the reason for the denial and your appeal rights.

§ 105–64.303 How do I appeal a denial to access a record?

If you are denied access to a record in whole or in part, you may file an administrative appeal within 30 days of the denial. The appeal should be in writing and addressed to: GSA Privacy Act Officer (CIB), General Services Administration, 1800 F Street NW, Washington DC 20405. Mark both the envelope and the appeal letter ''Privacy Act Appeal.''

§ 105–64.304 How are administrative appeal decisions made?

The GSA Privacy Act Officer will conduct a review of your appeal by consulting with legal counsel and appropriate officials. The Privacy Act Officer may grant record access if the appeal is granted. If the decision is to reject the appeal, the Privacy Act Officer will provide all pertinent information about the case to the Deputy Administrator and ask for a final administrative decision. The Deputy Administrator may grant access to a record, in which case the Privacy Act Officer will notify you in writing, and the system manager will make the record available to you. If the Deputy Administrator denies the appeal, he or she will notify you in writing of the reason for rejection and of your right to a judicial review. The administrative appeal review will take no longer than 30 workdays after the Privacy Act Officer receives the appeal. The Deputy Administrator may extend the time limit by notifying you in writing of the extension and the reason for it before the 30 days are up.

§ 105–64.305 What is my recourse to an appeal denial?

You may file a civil action to have the GSA administrative decision overturned within two years after the decision is made. You may file in a Federal District Court where you live or have a principal place of business, where the records are maintained, or in the District of Columbia.

Subpart 105–64.4—Amending a Record

§ 105–64.401 Can I amend my record?

You may request to amend your record by writing to the system manager with the proposed amendment. Mark both the envelope and the letter ''Privacy Act Request to Amend Record.''

§ 105–64.402 What records are not subject to amendment?

You may not amend the following records under the law:

(a) Transcripts of testimony given under oath or written statements made under oath.

(b) Transcripts of grand jury proceedings, judicial proceedings, or quasi-judicial proceedings which constitute the official record of the proceedings.

(c) Pre-sentence reports that are maintained within a system of records but are the property of the courts.

(d) Records exempted from amendment by notice published in the **Federal Register**.

§ 105–64.403 What happens when I submit a request to amend a record?

The system manager will consult with the Head of Service or Staff Office or

Regional Administrator or their representatives, and legal counsel. They will determine whether to amend an existing record by comparing its accuracy, relevance, timeliness, and completeness with the amendment you propose. The system manager will notify you within 10 workdays whether your proposed amendment is approved or denied. In case of an expected delay, the system manager will acknowledge receipt of your request in writing and provide an estimate of when you may expect a decision. If your request to amend is approved, the system manager will amend the record and send an amended copy to you and to anyone who had previously received the record. If your request to amend is denied, the system manager will advise you in writing, giving the reason for denial, a proposed alternative amendment if possible, and your appeal rights. The system manager also will notify the GSA Privacy Act Officer of any request for amendment and its disposition.

§ 105–64.404 What must I do if I agree to an alternative amendment?

If you agree to the alternative amendment proposed by the system manager, you must notify the manager in writing of your concurrence. The system manager will amend the record and send an amended copy to you and to anyone else who had previously received the record.

§ 105–64.405 Can I appeal a denial to amend a record?

You may file an appeal within 30 workdays of a denial to amend your record by writing to the: GSA Privacy Act Officer (CIB), General Services Administration, 1800 F Street NW, Washington DC 20405. Mark both the envelope and the appeal letter ''Privacy Act Amendment Appeal.'' Appeals to amend records in a GSA employee's official personnel file will be sent to the Office of Personnel Management, Washington DC 20415.

§ 105–64.406 How will my appeal be handled?

The GSA Privacy Act Officer will consult with legal counsel and appropriate GSA officials concerning your appeal. If they decide to reject your appeal, the Privacy Act Officer will provide the Deputy Administrator with all pertinent information about the case and request a final administrative decision. The Deputy Administrator may approve your amendment, in which case the Privacy Act Officer will notify you in writing, and the system manager will amend the record and send an amended copy to you and anyone who had previously been provided with the record. If the Deputy Administrator denies the appeal, he or she will notify you in writing of the reason for denial, of your right to a judicial review, and of your right to file a Statement of Disagreement. The amendment appeal review will be made within 30 workdays after the Privacy Act Officer receives your appeal. The Deputy Administrator may extend the time limit by notifying you in writing of the reason for the extension before the 30 days are up.

§ 105–64.407 How do I file a Statement of Disagreement?

You may file a Statement of Disagreement with the system manager within 30 days of the denial to amend a record. The statement should explain why you believe the record to be inaccurate, irrelevant, untimely, or incomplete. The system manager will file the statement with your record, provide a copy to anyone who had previously received the record, and include a copy of it in any future disclosure.

§ 105–64.408 What is my recourse to a denial decision?

You may file a civil action to have the GSA decision overturned within two years after denial of an amendment appeal. You may file the civil action in a Federal District Court where you live or have a principal place of business, where the records are maintained, or in the District of Columbia.

Subpart 105–64.5—Disclosure of Records

§ 105–64.501 Under what conditions may a record be disclosed without my consent?

A system manager may disclose your record without your consent under the Privacy Act when the disclosure is: to GSA officials or employees in the performance of their official duties; required by the Freedom of Information Act; for a routine use stated in a **Federal Register** notice; to the Bureau of the Census for use in fulfilling its duties; for statistical research or reporting, and only when the record is not individually identifiable; to the National Archives and Records Administration (NARA) when the record has been determined to be of historical or other value that warrants permanent retention; to a U.S. law enforcement agency or instrumentality for a civil or criminal law enforcement purpose; under compelling circumstances affecting an individual's health and safety, and upon disclosure a notification will be sent to the individual; to Congress or its committees and subcommittees when the record material falls within their jurisdiction; to the Comptroller General or an authorized representative in the performance of the duties of the Government Accountability Office (GAO); under a court order; or to a consumer reporting agency under the Federal Claims Collection Act of 1966, 31 U.S.C. 3711.

§ 105–64.502 How do I find out if my record has been disclosed?

You may request an accounting of the persons or agencies to whom your record has been disclosed, including the date and purpose of each disclosure, by writing to the system manager. Mark both the envelope and the letter ''Privacy Act Accounting Request.'' The system manager will provide the requested information in the same way as that for granting access to records, see Subpart 105–64.2, providing no restrictions to disclosure or accounting of disclosures applies.

§ 105–64.503 What is an accounting of disclosures?

The system manager maintains an account of each record disclosure for five years or for the life of the record, whichever is longer. The accounting of disclosure information includes the name of the person or agency to whom your record has been provided, the date, the type of information disclosed, and the reason for disclosure. Other pertinent information, such as justifications for disclosure and any written consent that you may have provided, is also included. No accounting needs to be maintained for disclosures to GSA officials or employees in the performance of their duties, or disclosures under the Freedom of Information Act.

§ 105–64.504 Under what conditions will I be denied an accounting of disclosures?

The system manager will deny your request for an accounting of disclosures when the disclosures are to GSA officials or employees in the performance of their duties or disclosures under the Freedom of Information Act, for which no accounting is required; law enforcement agencies for law enforcement activities; and systems of records exempted by notice in the **Federal Register**. You may appeal a denial using the same procedures as those for denial of access to records, see Subpart 105–64.3.

Subpart 105–64.6—Establishing or Revising Systems of Records in GSA

§ 105–64.601 Procedures for establishing system of records.

The following procedures apply to any proposed new or revised system of records:

(a) Before establishing a new or revising an existing system of records, the system manager, with the concurrence of the appropriate Head of Service or Staff Office, will provide to the GSA Privacy Act Officer a proposal describing and justifying the new system or revision.

(b) The GSA Privacy Act Officer will submit a proposal to establish or revise the system to the President of the Senate, the Speaker of the House of Representatives, and the Director of the Office of Management and Budget (OMB) for evaluation at least 40 calendar days before the planned system establishment or revision date.

(c) The GSA Privacy Act Officer will publish in the **Federal Register** a notice of intent to establish or revise the system of records at least 30 calendar days before the planned system establishment or revision date.

(d) The new or revised system becomes effective 30 calendar days after the notice is published in the **Federal Register** unless submitted comments result in a revision to the notice, in which case, a new revised notice will be issued.

Subpart 105–64.7—Assistance and Referrals

§ 105–64.701 Submittal of requests for assistance and referrals.

Address requests for assistance involving GSA Privacy Act rules and procedures, or for referrals to system managers or GSA officials responsible for implementing these rules to: GSA Privacy Act Officer (CIB), General Services Administration, 1800 F Street N.W., Washington DC 20405.

Appendix A to Part 105–64—Addresses for Geographically Dispersed Records

Address requests for physically dispersed records, as noted in the system of records notices, to the Regional Privacy Act Coordinator, General Services Administration, at the appropriate regional GSA office, as follows:

New England Region (includes Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), 10 Causeway Street, Boston, MA 02222.

Northeast and Caribbean Region (includes New Jersey, New York, Puerto Rico, and Virgin Islands), 26 Federal Plaza, New York, NY 10278.

Mid-Atlantic Region (includes Delaware, Maryland, Pennsylvania, Virginia, and West Virginia, but excludes the National Capital Region), The Strawbridge Building, 20 North 8th Street, Philadelphia, PA 19107–3191.

Southeast-Sunbelt Region (includes Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee), Office of the Regional Administrator (4A), 77 Forsyth Street, Atlanta, GA 30303.

Great Lakes Region (includes Illinois, Indiana, Michigan, Ohio, Minnesota, and Wisconsin), 230 South Dearborn Street, Chicago, IL 60604–1696.

The Heartland Region (includes Iowa, Kansas, Missouri, and Nebraska), 1500 East Bannister Road, Kansas City, MO 64131–3088.

Greater Southwest Region (includes Arkansas, Louisiana, Oklahoma, New Mexico, and Texas), 819 Taylor Street, Fort Worth, TX 76102.

Rocky Mountain Region (includes Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming), U.S. General Services Administration, DFC, Bldg. 41, Rm. 210, P.O. Box 25006, Denver, CO 80225–0006.

Pacific Rim Region (includes Arizona, California, Hawaii, and Nevada), 450 Golden Gate Avenue, San Francisco, CA 94102–3400.

Northwest/Arctic Region (includes Alaska, Idaho, Oregon, and Washington), 400 15th Street SW, Auburn, WA 98001–6599.

National Capital Region (includes the District of Columbia; the counties of Montgomery and Prince George's in Maryland; the city of Alexandria, Virginia; and the counties of Arlington, Fairfax, Loudoun, and Prince William in Virginia), 7th and D Streets, SW, Washington, DC 20407.

[FR Doc. 06–669 Filed 1–23–06; 8:45 am]

BILLING CODE 6820–34–S

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2006–23651]

RIN 2127–AJ81

Federal Motor Vehicle Safety Standards; Controls, Telltales and Indicators

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

ACTION: Final rule; delay of effective date.

SUMMARY: In a final rule of August 17, 2005 (70 FR 48295), we updated our standard regulating motor vehicle controls, telltales and indicators. The standard specifies requirements for the location, identification, and illumination of these items. The rule extended the standard's telltale and indicator requirements to vehicles with a Gross Vehicle Weight Rating (GVWR) of 4,536 kg (10,000 pounds) and greater, updated the standard's requirements for multi-function controls and multi-task displays to make the requirements appropriate for advanced systems, and reorganized the standard to make it easier to read. The final rule announced an effective date of February 13, 2006, and a compliance date of February 13, 2006 for requirements applicable to vehicles under 4,536 kg (10,000 pounds) GVWR.

In response to a petition for extension of the effective date from the Alliance of Automobile Manufacturers (Alliance), this final rule announces a delay in the effective date to September 1, 2006. The additional time allows us to consider issues raised by the Alliance and other petitioners in petitions to reconsider certain items and identifications described in the August 17, 2005 final rule.

DATES: *Effective date:* The effective date of the rule amending 49 CFR 571.101 published at 70 FR 48295, August 17, 2005 is delayed until September 1, 2006.

Compliance date: The compliance date for the extension of the standard's telltale and indicator requirements to vehicles with a GVWR of 4,536 kg (10,000 pounds) or greater is September 1, 2013. The compliance date for all other requirements is delayed until September 1, 2006. Voluntary compliance is permitted as of August 17, 2005.

Petitions for reconsideration: Petitions for reconsideration of this final rule must be received not later than March 10, 2006.

ADDRESSES: Petitions for reconsideration of the final rule must refer to the docket and notice number set forth above and be submitted to the Administrator, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590, with a copy to Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: For non-legal issues you may call Ms. Gayle Dalrymple, Office of Crash Avoidance

Standards at (202) 366–5559. Her fax number is (202) 366–7002. For legal issues, you may call Ms. Dorothy Nakama, Office of the Chief Counsel at (202) 366–2992. Her fax number is (202) 366–3820. You may send mail to both of these officials at National Highway Traffic Safety Administration, 400 Seventh St., SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Background

NHTSA issued the original version of Federal Motor Vehicle Safety Standard (FMVSS) No. 101, *Controls and Displays*, in 1967 (32 FR 2408) as one of the initial FMVSSs. The standard applies to passenger cars, multipurpose passenger vehicles (MPVs), trucks, and buses. The purpose of FMVSS No. 101 is to assure the accessibility and visibility of motor vehicle controls and displays under daylight and nighttime conditions, in order to reduce the safety hazards caused by the diversion of the driver's attention from the driving task, and by mistakes in selecting controls.

At present, FMVSS No. 101 specifies requirements for the location (S5.1), identification (S5.2), and illumination (S5.3) of various controls and displays. It specifies that those controls and displays must be accessible and visible to a driver properly seated wearing his or her safety belt. Table 1, ''Identification and Illumination of Controls,'' and Table 2, ''Identification and Illumination of Displays,'' indicate which controls and displays are subject to the identification requirements, and how they are to be identified, colored, and illuminated.

Final Rule

In the final rule of August 17, 2005, NHTSA amended FMVSS No. 101 by extending the standard's telltale and indicator requirements to vehicles of Gross Vehicle Weight Rating (GVWR) 4,536 kilograms (10,000 pounds) and over, updating the standard's requirements for multi-function controls and multi-task displays to make the requirements appropriate for advanced systems, and reorganizing the standard to make it easier to read. Table 1 and Table 2 continue to include only those symbols and words previously specified in the controls and displays standard or in another Federal motor vehicle safety standard. However, both Tables 1 and 2 were reorganized to make the symbols and words easier to find.

The final rule announced an effective date of February 13, 2006 for requirements applicable to passenger cars, multipurpose passenger vehicles, trucks and buses under 4,536 kg GVWR.

Extension of Effective Date

In a petition dated October 3, 2005, the Alliance of Automobile Manufacturers (Alliance) petitioned for a delay in the final rule's effective date to September 1, 2006. The Alliance stated its position that the final rule ''imposes a number of new requirements that will become applicable to passenger cars and other light-duty vehicles effective February 13, 2006.'' The Alliance asked for the delay to give NHTSA enough time to respond to the Alliance's petition for reconsideration, filed as a separate document, and also dated October 3, 2005.

Although NHTSA stated that the final rule would not require design changes, but would relieve restrictions on vehicle manufacturers, the Alliance asserted that certain final rule provisions will require vehicle redesign that cannot be completed by the February 13, 2006 effective date. The Alliance stated: ''These new requirements are included in: S5.2.1; S5.3.2.2(b); S5.3.4(d); S5.4.3, and S5.5.2. In addition appropriate changes are needed to Table 1 and Table 2 along with their respective footnotes.'' The Alliance asserted that the additional time will allow NHTSA to review and take ''final action'' on the issues raised in the Alliance's petition for reconsideration.

After considering the rationale explaining the need to maintain the status quo while NHTSA considers the Alliance's petition for reconsideration, NHTSA has decided that it is in the public interest to grant the Alliance's petition. By delaying the effective date to September 1, 2006, NHTSA will be able to reconsider certain required items and identifications described in the August 17, 2005 final rule before they become mandatory. Manufacturers will not have to make vehicle redesigns that they have informed NHTSA they will not be able to complete by February 13, 2006. Since voluntary compliance has been permitted as of August 17, 2005, those manufacturers that are able to comply by February 13, 2006 may continue to do so. Moreover, because the safety benefits of the final rule are very small, there will be no measurable effect on safety as a result of this delay in effective date. Therefore, NHTSA delays the effective date of the final rule of August 17, 2005 (70 FR 48295) to September 1, 2006. We will also consider other timely petitions for reconsideration of this final rule that we have already received.

Rulemaking Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), provides for making determinations whether a 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 a ''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.

We have considered the impact of this rulemaking action under Executive Order 12866 and the Department of Transportation's regulatory policies and procedures. This rulemaking document was not reviewed by the Office of Management and Budget under E.O. 12866, ''Regulatory Planning and Review.'' The rulemaking action is also not considered to be significant under the Department's Regulatory Policies and Procedures (44 FR 11034; February 26, 1979).

For the following reasons, NHTSA concludes that this final rule will not have any quantifiable cost effect on motor vehicle manufacturers. This final rule delays from February 13, 2006 to September 1, 2006, the effective date for the FMVSS No. 101 final rule published on August 17, 2005. Since the delay in the effective date is intended to maintain the status quo while NHTSA considers the issues in the Alliance's petition for reconsideration, manufacturers will incur no costs as a result of the delay in the effective date. The August 17, 2005 final rule removed a regulatory restriction (for multi-function controls) requiring identification ''on or adjacent to'' the controls and provided for immediate optional voluntary compliance. Thus, manufacturers benefiting from the amendment to FMVSS No. 101's ''on or

adjacent'' to requirement will not be affected by the delay in the effective date. Also, because the safety benefits of this final rule are very small, there will be no measurable effect on safety as a result of this delay in effective date.

Because the economic effects of this final rule are so minimal, no further regulatory evaluation is necessary.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions). The Small Business Administration's regulations at 13 CFR part 121 define a small business, in part, as a business entity ''which operates primarily within the United States.'' (13 CFR 121.105(a)). No regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

The Head of the Agency has considered the effects of this rulemaking action under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The statement of the factual basis for the certification is that this final rule delays until September 1, 2006, the effective date of the final rule published on August 17, 2005. As earlier stated, no small business manufacturer will incur costs as a result of this final rule.

For these reasons, and for the reasons described in our discussion on Executive Order 12866 and DOT Regulatory Policies and Procedures, NHTSA concludes that this final rule will not have a significant economic impact on a substantial number of small entities.

C. National Environmental Policy Act

NHTSA has analyzed this rulemaking action for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

D. Executive Order 13132 (Federalism)

Executive Order 13132 requires NHTSA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' The Executive Order defines ''policies that have federalism implications'' to include regulations that have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, NHTSA may not issue a regulation with federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or the agency consults with State and local officials early in the process of developing the regulation. NHTSA also may not issue a regulation with federalism implications and that preempts State law unless the agency consults with State and local officials early in the process of developing the regulation.

NHTSA has analyzed this rulemaking action in accordance with the principles and criteria set forth in Executive Order 13132. The agency has determined that this rule will not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. This rule will not have any substantial effects on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials. The reason is that this final rule applies to motor vehicle manufacturers, and not to the States or local governments. Thus, the requirements of Section 6 of the Executive Order do not apply.

E. Executive Order 12988 (Civil Justice Reform)

Pursuant to Executive Order 12988 ''Civil Justice Reform,'' we have considered whether this final rule would have any retroactive effect. NHTSA concludes that this final rule will not have any retroactive effect. Under 49 U.S.C. 30103, whenever a Federal motor vehicle safety standard is in effect, a State may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. 49 U.S.C. 30161 sets forth a procedure for judicial review of final rules establishing, amending, or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

F. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995, a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid Office of Management and Budget (OMB) control number. This final rule does not require any collections of information, or recordkeeping or retention requirements as defined by the OMB in 5 CFR part 1320.

G. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272) directs NHTSA to use voluntary consensus standards in its regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies, such as the Society of Automotive Engineers (SAE). The NTTAA directs the agency to provide Congress, through the OMB, explanations when we decide not to use available and applicable voluntary consensus standards.

After conducting a search of available sources, we have determined that there is no applicable voluntary consensus standard for this final rule, which delays the effective date of the August 17, 2005 final rule amending FMVSS No. 101.

H. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires Federal agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by

State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million in any one year (adjusted for inflation with base year of 1995). Before promulgating a rule for which a written statement is needed, section 205 of the UMRA generally requires NHTSA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows NHTSA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the agency publishes with the final rule an explanation why that alternative was not adopted.

This rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of more than $100 million annually. Accordingly, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

I. Plain Language

Executive Order 12866 requires each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

—Have we organized the material to suit the public's needs?
—Are the requirements in the rule clearly stated?
—Does the rule contain technical language or jargon that is not clear?
—Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
—Would more (but shorter) sections be better?
—Could we improve clarity by adding tables, lists, or diagrams?
—What else could we do to make this rulemaking easier to understand?

If you have comments on the Plain Language implications of this final rule document, please address them to the DOT Docket Number cited in the heading of this notice.

J. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

Authority: 49 U.S.C. 322, 30111, 30115, 30166, and 30177; delegation of authority at 49 CFR 1.50.

Issued on: January 13, 2006.

Jacqueline Glassman,

Deputy Administrator.

[FR Doc. 06–537 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–59–P

Proposed Rules

Federal Register
Vol. 71, No. 15
Tuesday, January 24, 2006

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

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1493

RIN 0551–ZA00

Supplier Credit Guarantee Program

AGENCY: Commodity Credit Corporation (CCC), USDA.

ACTION: Advance Notice of Proposed Rulemaking (ANPR).

SUMMARY: This ANPR solicits comments on options to reform the USDA, CCC, Supplier Credit Guarantee Program (SCGP). The purpose of this ANPR is to invite suggestions on changes to reform the program to reduce the risk of default, improve the ability to effect a collection on defaulted obligations, and consider alternative program mechanisms and forms of payment obligations that are consistent with commercial export practices. The intent of this request is to seek comments on program reforms that would improve the SCGP's effectiveness and efficiency and lower costs.

DATES: Comments must be submitted on or before February 23, 2006.

ADDRESSES: You may submit comments, by any of the following methods: E-mail: *SCGP.ANPR@fas.usda.gov.*

Fax: (202) 690–1595 Attention: ''SCGP/ANPR Comments.''

Mail: William S. Hawkins, Director, Program Administration Division, Export Credits, Foreign Agricultural Service, U.S. Department of Agriculture, 1400 Independence Ave., SW., Stop 1031, Washington, DC 20250–1031.

Hand Delivery/Courier: 1400 Independence Ave., SW., Room 4083, Washington, DC 20250–1031.

All comments received will be available for public inspection at the above address during regular business hours.

FOR FURTHER INFORMATION CONTACT: William S. Hawkins, Director, Administration Division, at the address stated above. Telephone: (202) 720–3241.

SUPPLEMENTARY INFORMATION:

Background

The regulations for the SCGP became effective on August 30, 1996. The program became operational with an announcement for Mexico on that same day, providing coverage for high-value agricultural products such as fruits, vegetables, tree nuts, potatoes, wine, brandy, dairy products, and ice cream. The products made eligible were those that typically traded in smaller transactions and not commonly financed under the existing CCC Export Credit Guarantee Program (GSM–102). CCC viewed the SCGP as a means of supplementing the GSM–102 program and providing more flexibility and options in leveraging private sector credit.

Since 1981, the GSM–102 program has served as a means of guaranteeing the payment by foreign banks of credit extended by U.S. exporters or banks for agricultural commodity sales. The SCGP provides a similar guarantee for payment by importers when U.S. exporters' extend short-term credit, up to 180-days, in export sales. CCC developed the SCGP as an export credit alternative that did not require a letter of credit as a payment mechanism, would better accommodate smaller transaction sizes associated with containerized shipping, and would react to importers' general desire to obtain open-account terms of payment from U.S. exporters.

At inception, the SCGP offered a 50 percent guarantee in the event that an importer of U.S. agricultural commodities or products defaulted on an obligation to pay the exporter for the value of the goods sold. On December 3, 1997, CCC amended the commodity eligibility for the SCGP to include bulk commodities such as cotton, feed grains, oilseeds, protein meals, and wheat. On October 1, 1999, guaranteed coverage under the SCGP increased from 50 to 65 percent.

The SCGP relies upon the principle of risk-sharing between exporter and CCC to work. Exporters are often in a unique position to assess the ability of an importer to pay for an export transaction because of past contractual experience, access to importer's credit references, or specialized knowledge of the agricultural business sector in the importing country. Since inception, the instrument establishing the importer's obligation to pay the export value has been a promissory note form, prescribed by CCC and issued by the importer to the exporter. The U.S. exporter can hold the SCGP payment guarantee or assign the guarantee to a U.S. financial institution. In many cases, where the exporter has assigned SCGP payment guarantees to a U.S. financial institution, the exporter is paid the percentage guaranteed by CCC by that financial institution and retains the risk of payment by the importer. In other cases, the U.S. financial institution, in taking an assignment of the SCGP payment guarantee, may be willing to pay the exporter for the entire export value if that financial institution is able to make a credit assessment of the importer and is willing to accept the risk of default for the uncovered portion of the sale.

Overall, since 1997, CCC issued approximately $2.78 billion in credit guarantees under the SCGP supporting more than $4.3 billion in U.S. export sales of agricultural commodities and products. Mexico has dominated the SCGP as an import destination with more than 60 percent of the volume of activity, but other regions such as Central America, South East Asia, and the Caribbean have benefited and further growth in these regions is expected. The SCGP has supported the U.S. export of a variety of agricultural commodities and products ranging from bulk commodities such as feed grains, oilseeds, protein meals, rice, and cotton, but also including significant volumes of red meat, poultry, fruits, grocery store items, and other high value agricultural products.

From 1997 to 2004, the defaults experienced in the SCGP were manageable given the limited size of the SCGP at that time and the sporadic nature of the defaults incurred. However, in 2004 and 2005 CCC experienced significant defaults under the SCGP. In reaction to these increased defaults, CCC made improvements to its claims recovery process, but CCC continues to seek other means to reduce defaults and better recoveries.

CCC's interest in SCGP improvements also arises from the outcome of the recent World Trade Organization (WTO) dispute brought by Brazil against the

United States with respect to the CCC export credit guarantee programs, including SCGP. The WTO dispute panel's ruling requires CCC to charge premia that are adequate to cover the long-term operating costs and losses of the programs as a whole. In response, on July 1, 2005, CCC revised the premia for the export credit guarantee programs to reflect program default risk and operating costs. CCC is interested in exploring potential revisions to the structure, design, or operation of SCGP that can contribute to meeting this ''break-even'' goal, particularly by incurring fewer program losses.

We request interested parties to comment on the following specific questions under consideration for the SCGP. Interested parties may choose to address any or all of the questions listed or provide other comment. CCC's aim is to improve upon the SCGP's integrity, effectiveness, flexibility, and continued viability.

1. *Transaction Size Considerations:* What limit, if any, should be imposed on the value of transactions or the amount of exposure that CCC should take on the importer that would be consistent with commercial practices?

2. *Level of Guarantee Coverage:*

• Is the current level of guarantee coverage at 65 percent appropriate?

• If a higher level of guarantee coverage is desired, what measures should CCC adopt to better ensure that importers are capable of meeting their credit obligations?

• If CCC offered a lower level of guarantee coverage, at what point would one the SCGP no longer be a viable program for U.S. exporters?

3. *Assignments of Payment Guarantees:*

• Should CCC require assignment of the SCGP payment guarantee and risk?

• Should CCC permit, but not require the exporter to assign the SCGP payment guarantee risk?

• Should CCC not permit the exporter to assign the SCGP payment guarantee and risk?

4. *Alternative Payment Obligations:*

• Should CCC permit alternative forms of payment obligations that would change the obligor risk from the importer to a foreign bank? (Examples of such alternative payment obligation are: A banker's acceptance from an eligible foreign bank, a guarantee of an eligible foreign bank of the importer's obligation to pay, or a bank aval (obligation to pay) added to the importer's promissory note.)

• What are the estimated costs of requiring a foreign bank guarantee mechanism on the importer's obligation as stated in the question above?

5. *Collection Experiences on Foreign Bank Obligations:* What are U.S. exporters' or U.S. financial institutions' collection experiences in using banker's acceptances or avalized promissory notes?

6. *Risk Mitigation Techniques:*

• Should CCC permit the U.S. exporter or financial institution to mitigate their risk on the portion of the transaction value not covered by the SCGP payment guarantee?

• If CCC permits risk mitigation, what should CCC do to ensure that the risk-sharing principal is maintained and that all monies are shared, on a pro-rata basis, between CCC and the exporter/assignee?

7. *Standby Letters of Credit:*

• Should CCC require that the importer open a standby letter of credit to the exporter for a portion of the export value that could be drawn upon by the exporter and shared with CCC on a pro-rate basis in the event of the default?

• What costs might be expected if the importer were required to maintain a standby letter of credit associated with the SCGP transaction?

8. *Creditworthiness Assessment of Importers:*

• What are exporters' and U.S. financial institutions' experiences in their attempts to assess the creditworthiness of the importer using commercial credit reference services?

• Are there countries and regions where credit assessments on agricultural importers cannot be performed readily and reliably?

9. *Collections and Recoveries:*

• How can CCC best partner with the exporter and/or the financial institution that has accepted assignment of a SCGP payment guarantee in order to effect a collection?

• What other means should CCC employ in its recovery efforts on SCGP defaults?

10. *Other Concerns:* What other concerns, comments, or interests relating to the program regulations, mechanisms, and operations of the SCGP are important?

Consideration of Comments

Additional comments on other program modifications to the SCGP that are responsive to the principles outlined herein are encouraged. CCC will carefully consider all comments submitted by interested parties. After consideration of the comments received, CCC will consider what changes, if any, should be made to the SCGP. Some of the above-described changes would require additional notice and consideration of comments from interested parties via the rulemaking process. Other changes might be adopted by changing internal policies and procedures. Comments received will help the Department determine that extent and scope of any future rulemaking.

Authority: 7 U.S.C. 5602, 5622, 5661, 5662, 5663, 5664, 5676; 15 U.S.C. 714b(d), 714c(f).

Signed at Washington, DC, on December 16, 2005.

W. Kirk Miller,

General Sales Manager and Vice President, Commodity Credit Corporation.

[FR Doc. 06–610 Filed 1–23–06; 8:45 am]

BILLING CODE 3410–05–M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 73

RIN 3150–AH60

Design Basis Threat; Reopening of Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Reopening of comment period.

SUMMARY: On November 7, 2005 (70 FR 67380), the Nuclear Regulatory Commission (NRC) published for public comment a proposed rule consolidating the supplemental requirements established by the April 29, 2003, design basis threat (DBT) orders with the existing DBT requirements in 10 CFR 73.1(a). Specific details of the attributes of the DBT to be protected against, which include both safeguards information (SGI) and classified information, are consolidated in adversary characteristics documents (ACDs) and Regulatory Guides (RGs). The proposed rule would revise the DBT requirements both for radiological sabotage and for theft or diversion of Strategic Special Nuclear Material (SSNM). ACDs and RGs provide guidance to licensees concerning the DBT for radiological sabotage, theft and diversion. They contain the specific details of the attributes of the threat which licensees need to know in order to evaluate what is necessary to comply with the proposed rule. On December 21, 2005, the Nuclear Energy Institute (NEI) requested a 30 day extension to the public comment period. Their request was based on the fact that though the proposed rule was published on November 7, 2005, the RGs and the ACDs were not available at that time. NEI requested copies of these documents. The NRC staff agreed to

provide these documents to the properly cleared individuals with a need to know, and NEI received the draft RGs and ACDs for power reactors on December 19, 2005. In view of the delay in providing the documents to the cleared personnel and in the interests of obtaining public comment from the broadest range of stakeholders, the comment period on the proposed rule is being extended for an additional 30 days from the original January 23, 2006, deadline to February 22, 2006.

DATES: The comment period has been extended and now expires on February 22, 2006. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attn: Rulemakings and Adjudications Staff.

Hand delivered comments should also be addressed to the Secretary, U.S. Nuclear Regulatory Commission, and delivered to 11555 Rockville Pike, Rockville, MD, between 7:30 a.m. and 4:15 p.m. Federal workdays.

You may also provide comments via the NRC's interactive rulemaking Web site: *http://ruleforum.llnl.gov*. This site also provides the availability to upload comments as files (any format), if your Web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415–5905; e-mail: *CAG@nrc.gov*.

Certain documents relating to this rulemaking, including comments received, may be examined at the NRC Public Document Room, 11555 Rockville Pike, Room O1–F21, Rockville, MD. The same documents may also be viewed and downloaded electronically via the rulemaking Web site: *http://ruleforum.llnl.gov*. Documents created or received at the NRC after November 1, 1999 are also available electronically at the NRC's Public Electronic Reading room on the Internet at *http://www.nrc.gov/NRC/ADAMS/index.html*. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. For more information, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 202–634–3273 or by e-mail to *pdr@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Manash K. Bagchi, Office of the Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone (301) 415–2905; e-mail *MKB2@nrc.gov* or Mr. Richard Rasmussen, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone (301) 415–8380; e-mail *RAR@nrc.gov*.

Dated at Rockville, Maryland, this 18th day of January, 2006.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 06–676 Filed 1–23–06; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–23659; Directorate Identifier 2005–NM–236–AD]

RIN 2120–AA64

Airworthiness Directives; Fokker Model F27 Mark 100, 200, 300, 400, 500, 600, and 700 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Fokker Model F27 Mark 100, 200, 300, 400, 500, 600, and 700 airplanes. This proposed AD would require revising the Limitations section of the airplane flight manual regarding the use of continuous ignition, fuel filter heating, and resetting circuit breakers during flight in certain conditions such as icing. This proposed AD results from reports of power loss on one or both engines in icing conditions. We are proposing this AD to advise the flightcrew that continuous ignition will not reduce the probability of power loss, and what action they must take to avoid this hazard. Loss of power in one or more engines during flight, if not prevented, could result in loss of control of the airplane.

DATES: We must receive comments on this proposed AD by February 23, 2006.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- *Fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Fokker Services B.V., P.O. Box 231, 2150 AE Nieuw-Vennep, the Netherlands, for service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed in the **ADDRESSES** section. Include the docket number ''FAA–2006–23659; Directorate Identifier 2005–NM–236–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov.*

Examining the Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket

Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the Docket Management System receives them.

Discussion

The Civil Aviation Authority—The Netherlands (CAA–NL), which is the airworthiness authority for The Netherlands, notified us that an unsafe condition may exist on all Fokker Model F27 Mark 100, 200, 300, 400, 500, 600, and 700 airplanes. The CAA–NL advises that since the start of operations with the Fokker F27 in 1958, there have been 13 reports of power loss on a single engine in icing conditions, and 9 reports of power loss on both engines in icing conditions. Investigation revealed that the use of continuous ignition in icing conditions while the auto-feather system is armed could cause damage to the engine turbine on both engines if there is an engine flame-out or loss of power. Continuous ignition used in these circumstances could cause an immediate relight with the propeller already in a course pitch and, as a consequence, damage the turbine and cause the engine to shut down. In this case, the engine cannot be restarted. The investigation also revealed that the requirements in the airplane flight manual (AFM) regarding the use of continuous ignition in certain operational conditions will not reduce the probability of loss of engine power. Loss of power in one or more engines during flight, if not prevented, could result in loss of control of the airplane.

Relevant Service Information

Fokker Service B.V. has issued Fokker Manual Change Notification—Operational Documentation (MCNO) MCNO–F27–020, dated June 1, 2004, to the Fokker F27 AFM. The MCNO revises the normal, abnormal, and emergency procedures sections of the AFM regarding the use of continuous ignition, fuel filter heating, and resetting circuit breakers during flight in certain operating conditions such as icing conditions. The CAA–NL mandated the AFM revisions and issued Dutch airworthiness directive 2004–122, dated October 28, 2004, to ensure the continued airworthiness of these airplanes in the Netherlands.

FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in the Netherlands and are type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA–NL has kept the FAA informed of the situation described above. We have examined the CAA–NL's findings, evaluated all pertinent information, and determined that we need to issue an AD for airplanes of this type design that are certificated for operation in the United States. Therefore, we are proposing this AD, which would require revising the normal, abnormal, and emergency procedures sections of the AFM regarding the use of continuous ignition, fuel filter heating, and resetting circuit breakers during flight in certain conditions such as icing conditions.

Costs of Compliance

This proposed AD would affect about 27 airplanes of U.S. registry. The AFM revision would take about 1 work hour per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $1,755, or $65 per airplane.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

Fokker Services B.V.: Docket No. FAA–2006–23659; Directorate Identifier 2005–NM–236–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by February 23, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Fokker Model F27 Mark 100, 200, 300, 400, 500, 600, and 700 airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from reports of power loss on one or both engines in icing conditions. We are issuing this AD to advise the flightcrew that continuous ignition will not reduce the probability of power loss, and what action they must take to avoid this hazard. Loss of power in one or more engines during flight, if not prevented, could result in loss of control of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Airplane Flight Manual (AFM) Revision

(f) Within 30 days after the effective date of this AD, revise the Limitations section of the Fokker F27 AFM by incorporating the information specified in Fokker Manual Change Notification—Operational Documentation (MCNO) MCNO–F27–020, dated June 1, 2004, into the Limitations section of the AFM.

Note 1: The actions required by paragraph (f) of this AD may be done by inserting a copy of MCNO MCNO–F27–020 into the Normal Procedures, Abnormal Procedures, and Emergency Procedures sections of the Fokker F27 AFM. When this MCNO, MCNO–F27–020, has been included in general revisions of the AFM, the general revisions may be inserted in the AFM, provided the relevant information in the general revision is identical to that in MCNO MCNO–F27–020.

Alternative Methods of Compliance (AMOCs)

(g)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(h) Dutch airworthiness directive 2004–122, dated October 28, 2004, also addresses the subject of this AD.

Issued in Renton, Washington, on January 13, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–795 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2005–23276; Airspace Docket No. 05–AAL–41]

Proposed Establishment of Class E Airspace; Minchumina, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to create Class E airspace at Minchumina, AK. One revised Standard Instrument Approach Procedure (SIAP) and two new SIAPs are being published for the Minchumina Airport. Adoption of this proposal would result in creation of Class E airspace upward from 700 feet (ft.) above the surface at Minchumina, AK.

DATES: Comments must be received on or before March 10, 2006.

ADDRESSES: Send comments on the proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2005–23276/ Airspace Docket No. 05–AAL–41, at the beginning of your comments. You may also submit comments on the Internet at *http://dms.dot.gov*. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

An informal docket may also be examined during normal business hours at the office of the Manager, Safety, Alaska Flight Service Operations, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587.

FOR FURTHER INFORMATION CONTACT: Gary Rolf, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; fax: (907) 271–2850; e-mail: *gary.ctr.rolf@faa.gov*. Internet address: *http://www.alaska.faa.gov/at*.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2005–23276/Airspace Docket No. 05–AAL–41.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of Notice of Proposed Rulemaking's (NPRM's)

An electronic copy of this document may be downloaded through the Internet at *http://dms.dot.gov*. Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov* or the Superintendent of Document's Web page at *http://www.access.gpo.gov/nara*.

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA–400, 800 Independence Avenue, SW., Washington, DC 20591 or by calling (202) 267–8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to the Code of Federal Regulations (14 CFR part 71), which would create Class E airspace at Minchumina, AK. The intended effect of this proposal is to create Class E airspace upward from 700 ft. above the surface to contain Instrument Flight Rules (IFR) operations at Minchumina, AK.

The FAA Instrument Flight Procedures Production and Maintenance Branch has developed two new SIAPs and revised one SIAP for the Minchumina Airport. The new approaches are; (1) Area Navigation (Global Positioning System) (RNAV (GPS)) Runway (RWY) 03, original; (2) RNAV (GPS) RWY 21, original. The revised SIAP is the Non-directional Beacon (NDB) RWY 03, amendment 3. New Class E controlled airspace extending upward from 700 ft. above the surface within the Minchumina Airport area would be established by this action.

The proposed airspace is sufficient to contain aircraft executing the new and revised instrument procedures at the Minchumina Airport.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 in FAA Order 7400.9N, *Airspace Designations and Reporting Points*, dated September 1, 2005, and effective September 15, 2005, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''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 is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart 1, section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it proposes to create Class E airspace sufficient in size to contain aircraft executing instrument procedures at Minchumina Airport and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

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.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9N, *Airspace Designations and Reporting Points*, dated September 1, 2005, and effective September 15, 2005, is to be amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Minchumina, AK [New]

Minchumina Airport, AK
(Lat. 63°53′10″ N., long. 152°18′07″ W.)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Minchumina Airport.

* * * * *

Issued in Anchorage, AK, on January 13, 2006.

Anthony M. Wylie,

Manager, Safety, Area Flight Service Operations.

[FR Doc. 06–599 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2005–ND–0002; FRL–8011–2]

Clean Air Act Approval and Promulgation of Air Quality Implementation Plan Revision for North Dakota; Revisions to the Air Pollution Control Rules; Delegation of Authority for New Source Performance Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to take direct final action approving certain revisions to the State Implementation Plan (SIP) as submitted by the Governor of North Dakota with a letter dated April 11, 2003. The revisions affect certain portions of air pollution control rules regarding permitting and prevention of significant deterioration. EPA is also providing notice that on July 27, 2005, North Dakota was delegated authority to implement and enforce certain New Source Performance Standards, as of January 31, 2004. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the preamble to the direct final rule. If EPA receives no adverse comments, EPA will not take further action on this proposed rule. If EPA receives adverse comments, EPA will withdraw the direct final rule and it will not take effect. EPA will address all public comments 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 must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

DATES: Written comments must be received on or before February 23, 2006.

ADDRESSES: Submit your comments, identified by Regional Material in EDOCKET (RME) ID Number R08–OAR–2005–ND–0002, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Agency Web site: http://docket.epa.gov/rmepub/.* On November 28, 2005, Regional Material in EDOCKET (RME), EPA's electronic public docket and comment system, was replaced by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov.* Therefore, you will be redirected to that site to access the docket EPA–R08–OAR–2005–ND–0002 and submit comments. Follow the on-line instructions for submitting comments.
- *E-mail: long.richard@epa.gov* and *platt.amy@epa.gov.*
- *Fax:* (303) 312–6064 (please alert the individual listed in the **FOR FURTHER**

INFORMATION CONTACT if you are faxing comments).

• *Mail:* Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 200, Denver, Colorado 80202–2466.

• *Hand Delivery:* Richard R. Long, Director, Air and Radiation Program, EPA Region 8, Mailcode 8P–AR, 999 18th Street, Suite 200, Denver, Colorado 80202–2466. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:55 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Please see the direct final rule which is located in the Rules Section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Amy Platt, Environmental Protection Agency, Region 8, 999 18th Street, Suite 200, Denver, CO 80202–2466, (303) 312–6449, *platt.amy@epa.gov.*

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action of the same title which is located in the Rules and Regulations Section of this **Federal Register**.

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

Dated: December 7, 2005.

Kerrigan G. Clough,

Acting Regional Administrator, Region 8.

[FR Doc. 06–628 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2005–MT–0001, FRL–8012–6]

Approval and Promulgation of Air Quality Implementation Plans; Montana; Revisions to the Administrative Rules of Montana; Proposed Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Montana on August 25, 2004. The revisions are to the Administrative Rules of Montana and correct internal references to state documents; correct references to, or update citations of, Federal documents; and make minor editorial changes. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the preamble to the direct final rule. If EPA receives no adverse comments, EPA will not take further action on this proposed rule. If EPA receives adverse comments, EPA will withdraw the direct final rule and it will not take effect. EPA will address all public comments 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 must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

DATES: Written comments must be received on or before February 23, 2006.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2005–MT–0001, by one of the following methods:

• *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

• E-mail: *long.richard@epa.gov* and *ostrand.laurie@epa.gov.*

• Fax: (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).

• Mail: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 200, Denver, Colorado 80202–2466.

• Hand Delivery: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 300, Denver, Colorado 80202–2466. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:55 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Please see the direct final rule which is located in the Rules Section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Laurie Ostrand, Air and Radiation Program, Mailcode 8P–AR, Environmental Protection Agency (EPA), Region 8, 999 18th Street, Suite 200, Denver, Colorado 80202–2466, (303) 312–6437, *ostrand.laurie@epa.gov.*

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action of the same title which is located in the Rules and Regulations section of this **Federal Register**.

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

Dated: December 7, 2005.

Kerrigan G. Clough,

Acting Regional Administrator, Region 8.

[FR Doc. 06–632 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2005–CO–0002; FRL–8010–1]

Clean Air Act Approval and Promulgation of Air Quality Implementation Plan Revision for Colorado; Long-Term Strategy of State Implementation Plan for Class I Visibility Protection

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the Governor of Colorado with a letter dated March 24, 2005. This revision updates the Long-Term Strategy of the Visibility SIP to establish strategies, activities, and monitoring plans that constitute reasonable progress toward the National visibility goal. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the preamble to the direct final rule. If EPA receives no adverse comments, EPA will not take further action on this proposed rule. If EPA receives adverse comments, EPA will withdraw the direct final rule and it will not take effect. EPA will address all public comments 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 must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions

of the rule that are not the subject of an adverse comment.

DATES: Written comments must be received on or before February 23, 2006.

ADDRESSES: Submit your comments, identified by Docket ID No. R08–OAR–2005–CO–0002, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Agency Web site*: *http://docket.epa.gov/rmepub/*. On November 28, 2005, Regional Material in EDOCKET (RME), EPA's electronic public docket and comment system, was replaced by an enhanced Federal-wide electronic docket management and comment system located at *http://www.regulations.gov*. Therefore, you will be redirected to that site to access the docket EPA–R08–OAR–2005–CO–0002 and submit comments. Follow the on-line instructions for submitting comments.
- *E-mail*: *long.richard@epa.gov* and *platt.amy@epa.gov*.
- *Fax*: (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- *Mail*: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 200, Denver, Colorado 80202–2466.
- *Hand Delivery*: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 200, Denver, Colorado 80202–2466. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:55 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Please see the direct final rule which is located in the Rules Section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Amy Platt, Environmental Protection Agency, Region 8, 999 18th St., Suite 200, Denver, Colorado, 80202, 303–312–6449, *platt.amy@epa.gov*.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action of the same title which is located in the Rules and Regulations section of this **Federal Register**.

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

Dated: December 7, 2005.

Kerrigan G. Clough,

Acting Regional Administrator, Region 8.

[FR Doc. 06–631 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 239, 257, and 258

[FRL–8024–1]

Maine: Proposed Determination of Adequacy for the State Municipal Solid Waste Landfill (MSWLF) Permitting Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve the State of Maine's permit program for municipal solid waste landfills (MSWLF's) and to approve the State's approach of not allowing conditionally exempt small quantity generator (CESQG) hazardous waste to be sent to non-municipal, non-hazardous waste disposal units. Elsewhere in today's **Federal Register**, EPA is publishing a direct final rule that determines the adequacy of the State of Maine's municipal solid waste permitting program without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we get relevant written comments which oppose this determination of adequacy during the comment period, the decision will take effect. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect and this separate document in this proposed rules section of the direct final **Federal Register** will serve as the proposal to determine the adequacy of the State Municipal Solid Waste Landfill permitting program.

DATES: Send your written comments by February 23, 2006.

ADDRESSES: Send any written comments to Chuck Franks, EPA Region 1, One Congress Street, Suite 1100 (CHW), Boston, MA 02114–2023; telephone: (617) 918–1554; e-mail: *franks.chuck@epa.gov.* Documents related to EPA's decision regarding the Determination of Adequacy (the ''Administrative Record'') are available for inspection and copying during normal business hours at the following locations: (1) Monday through Thursday, 8:30 a.m. to 4:30 p.m. and Friday, 8:30 a.m. to 12:30 p.m., Maine Department of Environmental Protection (ME DEP), State House Station 17, Hospital Street, Augusta, Maine 04333. For review of Maine's application at the Maine Department of Environmental Protection, (ME DEP), one day advance notice is requested by ME DEP and may be made by calling (207) 287–2651; and (2) EPA New England—Region 1 Library, One Congress Street—11th Floor, Boston, MA 02114–2023, business hours: 10 a.m. to 3 p.m., Monday through Thursday, telephone number: (617) 918–1990.

FOR FURTHER INFORMATION CONTACT: Chuck Franks, Hazardous Waste Unit, Office of Ecosystems Protection, EPA New England—Region 1, One Congress Street, Suite 1100 (CHW), Boston, MA 02114–2023; telephone: (617) 918–1554; e-mail: *franks.chuck@epa.gov.*

SUPPLEMENTARY INFORMATION: For additional information, please see the direct final rule published in the ''Rules and Regulations'' section of this **Federal Register**.

Dated: December 27, 2005.

Robert W. Varney,

Regional Administrator, EPA New England.

[FR Doc. 06–626 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 270

[Docket No. 040720212–4212–01; I.D. 040204A]

RIN 0648–AS09

Fish and Seafood Promotion Act Provisions; Seafood Marketing Councils

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: In 1989, NMFS issued a final rule enacting the Fish and Seafood Promotion Act of 1986 (Act), as it pertains to Seafood Marketing Councils (Councils), for one or more species of fish or fish products. That rule, along with a large number of other rules and regulations unused or little used, was stricken from the Code of Federal Regulations (CFR) as part of a government-wide Presidential regulatory reform effort. Although the implementing regulations were

withdrawn from the CFR, the Act remains in effect. In response to renewed industry support for marketing and promotion-related activities, NMFS proposes regulations implementing the Act governing the establishment and operation of marketing Councils. Therefore, the intent of the proposed rule is to responsibly implement the Act to be consistent with NMFS' goals and mission statement. That is, to ensure that NMFS stewardship goal is not jeopardized while increasing benefits from domestic fisheries. Several revisions to the 1989 implementing regulations are proposed in this document in order to comply with new regulatory and/or legal requirements.

DATES: Comments on this proposed rule are requested, and must be received no later than 5 p.m., local time, February 23, 2006.

ADDRESSES: Written comments on this proposed rule should be sent by any of the following methods:

• E-mail: *SMCcomments@noaa.gov*. Include in the subject line the following: ''Comments on the Proposed Rule for Seafood Marketing Councils;''

• Federal e-Rulemaking Portal: *http://www.regulations.gov*;

• Mail: Paper, disk, or CD-ROM comments should be sent to Gordon J. Helm, Acting Director, Office of Constituent Services, Room 9553, SSMC3, 1315 East-West Highway, Silver Spring, MD 20910; and

• Fax: (301) 713–2384.

Copies of the Regulatory Impact Review are available from Gordon Helm. The Initial Regulatory Flexibility Analysis (IRFA) is contained in the Classification section of this proposed rule.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this rule should be submitted to Gordon Helm (see **ADDRESSES**) and to David Rostker, Office of Management and Budget (OMB), by e-mail at *David_Rostker@omb.eop.gov*, or fax to (202) 395–7285.

FOR FURTHER INFORMATION CONTACT: Gordon J. Helm, Office of Constituent Services, telephone: (301) 713–2379 or E-mail: *Gordon.J.Helm@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Fish and Seafood Promotion Act of 1986 (16 U.S.C. 4001 *et seq.*), enacted November 14, 1986, authorizes the creation of Seafood Marketing Councils. The Act provides authority to the Secretary of Commerce (Secretary) to: Establish Councils that would develop strategies and implement measures to better inform consumers; promote the utilization of one or more species of fish or fish products; enter into agreements with eligible members of the seafood industry; fund referenda to establish and terminate species-specific Councils; and establish quality standards, attend Council meetings, and approve seafood marketing plans.

In 1986, when Congress enacted the Act, it found that: (1) The commercial fishing industry of the United States significantly contributed to the national economy, and could make a great contribution if fish resources within the United States Exclusive Economic Zone were more fully utilized; (2) the commercial fisheries of the United States provided significant employment in coastal areas and in processing and distribution centers; (3) fish contributed an important nutritional component to the American diet; (4) increased consumption of seafood in the United States could significantly lower the risk of many cardiovascular diseases; (5) Federally supported development programs for commercial fisheries were unable to meet present and future marketing needs; (6) many fish species were underutilized by the United States fishing industry because of underdeveloped markets; and (7) the United States fishing industry had the potential to expand greatly its contribution to interstate and foreign commerce, favorably affecting the balance of trade.

A final rule implementing the Act was published in the **Federal Register** on December 7, 1989 (54 FR 50504). A National Seafood Marketing Council (National Council) was established under the Act. The National Council was authorized to enter into agreements with applicants to fund referenda to establish and terminate species-specific marketing councils. However, no species-specific marketing councils were established and the National Council was disbanded. In 1996, the regulations implementing the Act were removed from the CFR as part of the government-wide Presidential regulatory reform effort.

The 1986 Congressional findings and statement of purpose (16 U.S.C. 4001 & 4002) concerning the value of the commercial fisheries to the United States may still apply today. Furthermore, industry interest and support for seafood marketing and promotion-related activities has been expressed. Niche marketing programs have been initiated by both the Pacific salmon harvesters in Alaska and by the Wild American Shrimp organization in the southern Atlantic and Gulf of Mexico states. Additional interest has been expressed by U.S. tuna processors who are also facing declining market shares due to foreign competition. The accompanying IRFA and RIR indicate that at least twelve fish species could benefit from the development of organized marketing programs. Marketing and promotion plans prepared by a Council would be designed to increase the general demand for fish and fish products by encouraging, expanding, and improving the marketing and utilization of fish and fish products both in domestic or foreign markets, through consumer education, research, and other marketing and promotion activities. Therefore, NMFS proposes to implement regulations that would provide the foundation for the establishment, organization, and practices of the Councils. This proposed rule identifies the role of the Secretary of Commerce, who has delegated authority to NMFS, in the establishment and administration of the Council process. Also provided are guidelines for preparation of the application package including specific requirements for proposed charters, identification of sector participants who are eligible to vote in the referendum, descriptions of how a referendum would be conducted, and determination of payment and/or refunding of assessment fees. Also addressed are petitions of objection related to assessment fees and petitions for the dissolution of a Council. NMFS suggests that interested persons also read the Act along with this document for additional information.

Content and Submission of Application Package to Establish A Council

An application package submitted to NMFS to establish a Council would consist of the following information: (1) An application requesting NMFS to establish a Council; (2) a list of sector participants who are eligible to vote in the referendum; (3) a proposed charter under which the proposed Council would operate; and (4) an IRFA and/or other analytical documentation addressing the requirements of the Regulatory Flexibility Act, E.O. 12866, the National Environmental Policy Act, and other information NMFS considers necessary or appropriate for the review and approval of the application.

One signed original and two copies of the completed application package should be submitted to the Assistant Administrator for Fisheries, 1315 East-West Highway, Silver Spring, MD 20910. NMFS would acknowledge receipt of the application package and

contact the applicant if further information is required.

1. Application.

The application should be comprised of the signatures or corporate certifications of no less than three sector participants in each sector who collectively accounted for, in the previous 12-month period, not less than 10 percent of the value of the fish or fish products that were handled by each such sector during that period. For purposes of the Act and this proposed rule, ''sector'' means: (A) The sector consisting of harvesters; (B) the sector consisting of importers; (C) the sector consisting of marketers; (D) the sector consisting of processors; (E) the sector consisting of receivers; or (F) the consumer sector consisting of persons professionally engaged in the dissemination of information pertaining to the nutritional benefits and preparation of fish and fish products.

Persons who meet these minimum requirements would be eligible to submit an application to NMFS to establish a Council. The application should include a statement that, if established, the Council would have sufficient resources, e.g., cash, donated office space, services, supplies, etc., available for initial administrative expenditures pending collection of assessments.

2. List of Sector Participants Eligible to Vote in the Referendum.

The applicant would provide a list of sector participants, to the extent practicable, identifying the business name and address of all sector participants that the applicant believes meet the requirements for eligibility to vote in the referendum on the adoption of the proposed charter. The list would include all sectors in which a sector participant meets the eligibility requirements. If the sector participant has more than one place of business located within the geographic area of the Council, all such places would be listed and the primary place of business should be designated. At the time of submission of the application the referendum list of sector participants would also contain the list of required signatures or corporate certifications.

NMFS acknowledges that development of the list of sector participants meeting the minimum requirements stated in the proposed charter may be difficult. The Act requires the applicant, to the extent practicable, to develop such a list. NMFS would, to the extent practicable, verify the validity of the applicant's list, which may require adding or deleting names provided by applicant. At the request of an applicant, NMFS would provide available information in its possession of a non-proprietary nature to assist in developing this list.

The Council, if approved, would be required to maintain a list of sector participants. The Council would need a current list of sector participants in each sector represented on the Council, particularly for the purposes of collecting assessments and voting in referenda.

3. Charter.

At a minimum the text of the proposed charter would contain the following information:

(1) The name of the Council and a provision proclaiming its establishment;

(2) A declaration of the purposes and objectives of the Council;

(3) A description of the species of fish and fish products, including the scientific and common name(s), for which the Council would implement marketing and promotion plans under the Act;

(4) A description of the geographic area (state(s)) within the United States covered by the Council;

(5) The identification of each sector and the number and terms of representatives for each sector that would be voting members on the Council;

(6) The identification of those sectors (which would be required to include a sector consisting of harvesters, a sector consisting of receivers, and, if subject to assessment, a sector consisting of importers) eligible to vote in the referendum to establish the Council;

(7) For each sector a threshold level specifying the minimum requirements, as measured by income, volume of sales, or other relevant factors, that a person engaging in business in the sector would be required to meet in order to participate in a referendum;

(8) A description of the rationale and procedures for determining assessment rates based on a fixed amount per unit of weight or measure, or on a percentage of value of the product handled;

(9) The proposed rate or rates that would be imposed by the Council on receivers and, if subject to assessment, importers during its first year of operation;

(10) The maximum amount by which an assessment rate for any period may be raised above the rate applicable for the immediately preceding period;

(11) The maximum rate or rates that would be imposed by a Council on receivers or importers during the operation of the Council;

(12) The maximum limit on the amount any one sector participant would be required to pay under an assessment for any period;

(13) The procedures for providing refunds to sector participants subject to assessments who request refunds in accordance with the time limits;

(14) A provision setting forth the voting procedures by which votes would be cast by proxy;

(15) A provision that the Council would have voting members representing the harvesting, receiving and, if subject to assessment, importing sectors;

(16) A provision setting forth the definition of a quorum for making decisions on Council business and the procedures for selecting a chairperson of the Council;

(17) A provision that members of the Council would serve without compensation, but would be reimbursed for reasonable expenses incurred in performing their duties as members of the Council;

(18) A provision containing a requirement for submission of documentation as requested by NMFS for purposes of evaluating the performance of proposed marking plans and the Council's related performance;

(19) A provision containing the minimum number of participants that would be needed for sustained operations that cannot receive assessment refunds;

(20) A provision acknowledging that NMFS would have the right to participate in Council meetings;

(21) A provision that NMFS would have final approval authority over proposed marketing plans and Council actions;

(22) A provision containing a requirement for the Council to arrange for a complete audit report to be conducted by an independent public accountant and submitted to NMFS at the end of each fiscal year;

(23) A provision containing a requirement for the Council to conduct a market assessment based on economic, market, social and demographic, and biological information as deemed necessary by NMFS; and

(24) A provision containing a requirement for the Council to update the list of sector participants eligible to vote in a referendum on an annual basis.

4. Analytical Documentation.

Analytical documentation would be required as part of the application package in order to determine the impacts of the proposed Council under applicable law. Individual Councils, once established, may impact on small entities, but the impacts could not be determined until the charter is drafted with ranges of assessments based on volume, income, etc., of sector participants to be involved in the

Council. Specifically, the imposition of assessments on certain members of the industry would have an effect on a firm's financial situation. Any other costs or requirements which the Council would impose on industry would also have to be considered and analyzed. Since these parameters would vary with each application, a determination of impact would be made on a case-by-case basis. Therefore, the applicant would provide an IRFA and/or other analytical documentation addressing the requirements of the Regulatory Flexibility Act, E.O. 12866, the National Environmental Policy Act, and other information NMFS considers necessary or appropriate for the review and approval of the application. This other necessary and appropriate information required for the review of the application includes, but is not limited to, an analysis of the primary, secondary, and tertiary affects of increasing demand for seafood. This information would have to be incorporated into the NEPA analysis to determine if a proposed council or its marketing program is consistent with NMFS conservation goals, national standards, other national guidelines, and would have to be demonstrated to be consistent with Federal standards and guidelines on nutrition and health.

Initial Decision

NMFS would make an initial decision on the application, list of sector participants eligible to vote in the referendum, charter, and other required analytical documentation such as the IRFA within 180 days of receipt. NMFS would determine if the application package is complete and complies with all of the requirements set forth in the implementing regulations, the Act, and other applicable law.

If a negative determination is made, NMFS would advise the applicant in writing of the reasons for the negative determination, such as missing documentation. The applicant may submit a revised application package for reconsideration. NMFS would then have 180 days from receipt of the revised application package to make a determination.

If an affirmative decision is made, the Act requires NMFS to publish (by such means as will result in wide publicity in regions affected by the proposed charter) the text of the proposed charter and a list of those sector participants eligible to vote in the referendum and provide for public comment, including the opportunity for public meeting and to amend the list of sector participants. NMFS intends to publish notification in the **Federal Register** and provide a formal comment period. That notice would serve as a proposed rule thus triggering the requirements of the Regulatory Flexibility Act. As is standard practice, NMFS in the **Federal Register** document would announce availability of the IRFA and/or other analytical documents for review and comment.

Referendum on Adoption of Proposed Charter

1. Sector Participant Vote

NMFS would conduct a referendum on the adoption of the proposed charter within 90 days of its initial affirmative decision. The referendum would be conducted among all sector participants that meet the requirements for eligibility to participate in the referendum, as identified in the proposed charter. The vote may be made by any responsible officer, owner, or employee representing a sector participant.

A vertically integrated seafood company may qualify to vote in more than one sector, depending on the requirements established for each sector by the Council. However, only one vote may be cast by each sector participant who is eligible to vote, regardless of the number of individuals that make up the ''sector participant'' and how many sectors the participant is engaged in. Therefore, it is requested that petitioners specify in the list of sector participants all sectors for which a sector participant meets the eligibility requirements to vote in a referendum. The ballot for each referendum would request that each person voting certify in which sector he/she is voting in that particular referendum. This certification by sector participants voting in a referendum will be important to NMFS and the Council in order to determine the success or failure of a referendum, since the percentage of sector participants voting favorably and the value of fish products they handled in a sector will determine the outcome.

The referendum to establish a Council would pass if votes cast in favor of the proposed charter constitute a majority of the sector participants voting in each and every sector. Further, the majority must collectively account for, in the preceding 12-month period, at least 66 percent of the value of the fish and fish products described in the proposed charter that were handled during this period, in that sector, and by those who met the eligibility requirements to vote in the referendum. If the referendum passes, NMFS could establish a Council and approve the proposed charter. If a referendum fails to pass in any sector of the proposed Council, NMFS would not establish the Council or approve the proposed charter. NMFS would notify the applicants of the results of the referendum and publish the results of the referendum in the **Federal Register**.

2. Costs of Conducting a Referendum

NMFS would initially pay all costs related to the conduct of the referendum to establish a Council. Once an application has been approved, NMFS would estimate the cost of conducting the referendum, notify the applicants, and request that they post a bond or provide other applicable security, such as a cashier's check, to cover costs of the referendum. Although the cost of each referendum would vary according to the size of the Council, there would be some cost categories that would be common to the conduct of all referenda, e.g., verification of the list of sector participants, publication of the application, charter, and list of sector participants in the **Federal Register**, printing and postage costs for the ballots, etc. In the event a public hearing is requested, this would also add to the cost.

After the referendum has been conducted, NMFS would inform the applicants of the exact cost. If the referendum is approved and the proposed charter is adopted, the Council would be required to reimburse NMFS for the total actual costs of the referendum within 2 years after establishment of the Council. This amount would be paid for from assessments collected by the Council. If a referendum fails to result in establishment of a Council, NMFS would immediately recover all expenses incurred from the bond or security posted by applicants. In either case, such expenses would not include salaries of government employees or other administrative overhead, but would be limited to those additional direct costs incurred in connection with conducting the referendum to establish a Council.

Appointments, Terms, Vacancies, and Removal of Council Members

Within 30 days after a Council is established, NMFS would solicit nominations for Council members from the sector participants represented on the Council in accordance with the approved charter. The members of each Council would be individuals who, by reason of their occupational or other experience, scientific expertise, or training, are knowledgeable with regard to the activities of the sector which the individual would represent on the Council. To the extent practicable, the nominations should result in equitable representation for the constituent regions.

NMFS would appoint the members of the Council from among the nominees within 60 days. The term for members would be 3 years. Initially, to ensure continuity, half of the members' terms would be 2 years and half would be 3 years. Reappointments would be permissible.

Vacancies on a Council would be filled within 60 days after the vacancy occurs, in the same manner in which the original appointment was made. A member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed would be appointed only for the remainder of that term.

Council members would serve without compensation but would be reimbursed for their reasonable expenses incurred in performing their duties as members of the Council.

NMFS would remove a member of a Council if the Council recommended, by not less than two-thirds of its members, removal for cause. Such a recommendation of a Council should be in writing and accompanied by a statement of the reasons upon which the recommendation would be based.

Continued Operation of the Council

Continued operation of a Council would be at the discretion of NMFS and subject to NMFS' annual review of a market assessment prepared by the Council and evaluation of Council performance. Increases in product prices would not be the sole criteria for determining the effectiveness of a marketing program. The Council must demonstrate that the marketing plan would not adversely impact those fisheries for which conservation and management measures are necessary to prevent overfishing and rebuild overfished stocks, i.e., the market plan would be designed to increase profits rather than increase harvest. The marketing plan should also demonstrate that conservation and management efforts in other fisheries are not adversely affected, but the Secretary may use the primary, secondary, or tertiary impacts in evaluating whether the Council should be allowed to continue operating. Where measures have been implemented to reduce the overall harvest in a fishery, the marketing plan should clearly identify how stock conservation harvest capacity reduction would not be adversely impacted. Council support of the regional fishery management council's adoption of dedicated or controlled access programs, for example but not limited to programs such as Individual Fishing Quota, moratorium on new entrants into a fishery, and other effort control measures, would be programs that comply with this standard. In addition, NMFS would retain the authority to determine if the continued operation of a Council would be in the public interest. Councils would be required to meet performance standards approved by NMFS that demonstrate that marketing and promotion programs are effective in increasing consumer demand for species-specific seafood products. Councils would also be required to conduct market assessments based on economic, market, social and demographic, and biological information as deemed necessary by NMFS. This information and data would be provided to NMFS with the market assessment for review and verification of results and analysis and may be used by NMFS subject to normal rules and guidelines for industry generated data and information.

Reports and Marketing Plans

Councils would be required to submit annual plans and budgets for species-specific marketing and promotion plans, including when applicable consumer education, research, and other activities of the Councils. Councils would also be required to submit progress reports on implementation of the marketing and promotion plans and a financial reports with respect to the receipt and disbursement of funds entrusted to it. NMFS would require a complete audit report to be conducted by an independent public accountant and submitted to NMFS at the end of each fiscal year.

The Council must maintain reports, books, and records for a minimum of 3 years, even if the Council is terminated in less than 3 years. The purpose of this requirements is to enable NMFS to ensure that all remaining business of the terminated Council is concluded in an orderly manner. The 3-year time limit is in accordance with the Office of Management and Budget guidelines for implementing the Paperwork Reduction Act.

Assessments

Councils would be funded through voluntary assessment of the industry represented on the Councils. Assessments would be imposed on sector participants in the receiving sector or the importing sector or both as specified in the approved Council charter. Assessment rates would be based on value that may be expressed in monetary units or units of weight or volume. Once a participant declines to pay an assessment, or elects not to participant in a Council, no future assessments will be imposed. With the concurrence of the Secretary, a Council would establish the applicable assessment for those seeking to rejoin or participate in a Council at a future time.

1. Sector Participant and Related Assessment.

An assessment on sector participants in the receiving sector would be in the form of a percentage of the value or a fixed amount per unit of weight or volume of the fish described in the charter when purchased by receivers from fish harvesters.

An assessment on sector participants who own fish processing vessels and harvest the fish described in the charter would be in the form of a percentage of the value or on a fixed amount per unit of weight or volume of the fish in the charter that is no less than the value if such fish had been purchased by a receiver other than the owner of the harvesting vessel.

An assessment on sector participants in the importing sector would be in the form of a percentage of the value that an importer pays to a foreign supplier, as determined for the purposes of the customs laws, or a fixed amount per unit of weight or volume, of the fish or fish products described in the charter when entered or withdrawn from warehouse for consumption, in the customs territory of the United States by such sector participants.

2. Notice of Assessment to Sector Participant

The Council would provide notice to a sector participant subject to assessment that the assessment is due. The notice of assessment would contain:

a. A specific reference to the provisions of the Act, regulations, charter, and referendum that authorize the assessment;

b. The amount of the assessment;

c. The period of time covered by the assessment;

d. The date the assessment would be due and payable, which would not be earlier than 30 days from the date of the notice;

e. The form(s) of payment; and

f. To whom and where the payment would be made.

g. Notification of the right to seek review of the assessment by filing a written petition of objection with NMFS at any time during the time period to which the assessment applies in accordance with the procedures in § 270.19.

h. Notification of the right to request a hearing on the petition of objection.

i. Notification of the a right to request a refund of the assessment; the request for a refund may be submitted for not less than 90 days from the date of the

assessment; and the Council would make the refund within 60 days from the date of the receipt.

Persons subject to an assessment would be required to pay the assessment on or before the date due, unless they have demanded a refund or filed a petition of objection with NMFS under § 270.21. However, person who have demanded a refund under § 270.22 or filed a petition of objection under § 270.21 may submit proof of these actions in leu of payment. In the case of a petition of objection, NMFs will inform the Council and the petitioner of its finding at which time petitioner must pay the revised assessment if applicable.

3. Petition of Objection

Requests for NMFS to modify or take other appropriate action regarding the assessment may be made by filing with NMFS a written petition of objection. Any sector participant subject to an assessment may file a written petition with NMFS alleging that the assessment, the plan approved upon which the assessment is based, or any obligation imposed under the plan, is not in accordance with the law. A petition of objection may request NMFS to modify or take other appropriate action regarding the assessment or plan. A petition may be filed only during the time period to which the assessment applies. The petitioner may also request a formal hearing. Following the hearing, or if no hearing is held, as soon as practicable, NMFS would decide the matter and serve written notice of the decision to the petitioner and the Council. NMFS's decision would be based on a consideration of all relevant documentation and other evidence submitted, and would constitute the final administrative decision and order of the agency.

4. Refund of Assessment

Pursuant to 16 U.S.C. 4014, any sector participant who pays an assessment under the Act may demand and must promptly receive from the Council a refund of the assessment. A demand for refund must be made in accordance with procedures in the approved charter and within the time limits prescribed by the Council and approved by NMFS. Procedures to provide such a refund would be established before any such assessment would be collected. The refund procedures would allow the sector participant to request a refund for not less than 90 days from the date of the assessment and the Council would make the refund within 60 days from the date of the receipt of the request for the refund. Once a refund has been requested by a sector participant and paid by the Council, that sector participant would no longer participate in a referendum or other business of the Council during the remainder of the assessment rate period. However, if assessments should be paid during a future assessment rate period and no refund is requested, that sector participant would be able to again participate in a referendum or other business of the Council.

Quality Standards

Each Council may develop and submit to NMFS for approval, or upon the request of a Council, NMFS would develop quality standards for the species of fish or fish products described in the approved charter. Any quality standard developed should be consistent with the purposes of the Act. A quality standard should be adopted by a Council by a majority of its members following a referendum conducted by the Council among sector participants of the concerned sector(s). In order for a quality standard to be brought before Council members for adoption, the majority of the sector participants of the concerned sector(s) must vote in favor of the standard. Further, according to the best available data, the majority must collectively account for, in the preceding 12-month period, not less than 66 percent of the value of the fish or fish products described in the charter that were handled during such period in that sector by those who meet the eligibility requirements to vote in the referendum. Councils may develop quality standards establishing the criteria for the fish or fish products being promoted. The Council would submit a plan to conduct the referendum on the quality standards to NMFS for approval at least 60 days in advance of such referendum date. The plan would consist of the following:

(1) Date(s) for conducting the referendum;

(2) Method (by mail or in person);

(3) Copy of the proposed notification to sector participants informing them of the referendum;

(4) List of sector participants eligible to vote;

(5) Name of individuals responsible for conducting the referendum;

(6) Copy of proposed ballot package to be used in the referendum; and

(7) Date(s) and location of ballot counting.

An official observer appointed by NMFS would be allowed to be present at the ballot counting and any other phase of the referendum process, and may take whatever steps NMFS deems appropriate to verify the validity of the process and results of the referendum.

Quality standards developed must meet or exceed the U.S. Food and Drug Administration's minimum requirements for fish and fish products for human consumption and must be consistent with applicable standards of the U.S. Department of Commerce (National Oceanic and Atmospheric Administration) or other recognized Federal standards and/or specifications for fish and fish products.

The intent of quality standards must not be to discriminate against importers who are not members of the Council. Quality standards must not be developed for the purpose of creating non-tariff barriers. Such standards must be compatible with U.S. obligations under the General Agreement on Tariffs and Trade, or under other international standards deemed acceptable by NMFS.

No quality standard adopted by a Council can be used in false or misleading advertising or promotion of fish or fish products. A quality standard may be adopted which requires sector participants to be in the U.S. Department of Commerce voluntary seafood inspection program.

With respect to a quality standard adopted under this section, the Council would develop and file with NMFS an official identifier in the form of a symbol, stamp, label or seal that would be used to indicate that a fish or fish product meets the quality standard at the time the official identifier is affixed to the fish or fish product, or is affixed to or printed on the packaging material of the fish or fish product. The use of such identifier would be governed by § 270.15.

Dissolution of a Council

1. Petition for Termination

No less than three sector participants in any one sector may file a petition to terminate a Council. The petition would be accompanied by a written document explaining the reasons for the petition. If NMFS initially determines that the petition is accompanied by the signatures, or corporate certifications, of no less than three sector participants in the sector who collectively accounted for, in the preceding 12-month period, not less than 20 percent of the value of the fish or fish products that were handled by that sector during the period, NMFS within 90 days after the initial determination, would conduct a referendum for termination of the Council among all sector participants in that sector.

NMFS would publish notification in the **Federal Register** of the referendum, including an explanation of the reasons for the petition for termination and any other relevant information NMFS considers appropriate. The notification

would be published at least 30 days prior to the referendum.

2. Referendum Vote on Termination

If the referendum votes which are cast in favor of terminating the Council constitute a majority of the sector participants voting and the majority, in the preceding 12-month period, collectively accounted for not less than 66 percent of the value of such fish and fish products the that were handled during that period by the sector who filed the petition, NMFS would by order terminate the Council effective as of a date by which the affairs of the Council would be concluded.

3. Cost of Referendum

NMFS would initially pay all costs of this referendum. However, prior to conducting the referendum, NMFS would require petitioners to post a bond or other security acceptable to NMFS in an amount which NMFS determines to be sufficient to pay any expenses incurred for the conduct of the referendum.

If a Council is terminated, NMFS, after recovering all expenses incurred for the conduct of the referendum, would take action as is necessary and practicable to ensure that moneys remaining in the account established by the Council are paid on a prorated basis to the sector participants from whom those moneys were collected. If a referendum fails to result in the termination of the Council, NMFS would immediately recover the amount of the bond posted by the petitioners.

If the amount remaining in the Council account is insufficient for NMFS to recover all expenses incurred for the conduct of the referendum, NMFS would recover the balance of the expenses from the petitioners that posted a bond.

Proprietary Business Data or Commercial Information

Commercial or financial information submitted to NMFS in compliance with any requirement or regulation related to the Act, implementing regulations, or other applicable law would be treated as proprietary or confidential and protected from public disclosure to the extent possible under applicable law (see 16 U.S.C. 4012(f)). However, NMFS may release or make public general or statistical statements based upon reports of a number of persons (in aggregate or summary form) which does not directly or indirectly disclose the identify or business of any individual or business who submits the information.

Classification

The proposed rule has been determined to be significant for the purposes of Executive Order 12866. The primary concern is that the market may have failed to provide information on the quality, safety, and availability of fishery products that is accurate and easily available to consumers. NMFS requests comments from the public on what market failures justifiy creation of seafood marketing councils, the degree to which industry structure affects these market failures, and whether this program is narrowly tailored to remedy those market failures.

NMFS prepared an IRFA that describes the economic impacts of this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained in the **SUMMARY** and **SUPPLEMENTARY INFORMATION** section of the preamble. This proposed rule does not duplicate, overlap, or conflict with other Federal rules.

Recordkeeping and Reporting Requirements

In addition to recordkeeping and reporting requirements required to create a Council, small entities could also be required to complete forms required to administer assessment fees, petition for a refund of assessment fees, or participate in any referendum under a specific Council's charter. NMFS believes the number of burden hours to small entities to meet Council obligations could range between 5 and 20 hours annually. This proposed rule does not implement a seafood marketing program, therefore, the Paperwork Reduction Act requirements are not triggered. However, there may be a need for additional burden hours once a Council's charter is accepted.

Description of Small Entities Affected by this Proposed Rule

The potential universe of entities affected by this action includes all harvesters, importers, marketers, and processors of seafood. With the exception of a small number of catcher-processor vessels, most harvesters are identified as small entities under the Regulatory Flexibility Act meeting a size standard of less than $3.5 million in gross receipts. Importers and marketers are characterized as small if the number of employees working in a typical pay period number are 100 or fewer while seafood processors employing 500 people or less are considered small. A Council could be made up of any combination of small or large firms depending upon the sector or sectors of a particular fishery the Council is representing. NMFS statistics indicate that there are approximately 17,679 harvesters, 935 processing plants, and 2,446 wholesale and marketing establishments that could be affected by this proposed rule.

Economic Impact Analysis

Overview

Despite a strong U.S. demand for fish and shellfish, the domestic seafood industry is faced with a number of challenges. The industry has been experiencing declining prices, sales, and earnings; increased input costs, particularly fuel; increasingly restrictive management; strong competition from imports and aquaculture; loss of access to supporting infrastructure (e.g., dock space); and numerous health advisories regarding seafood consumption. The nominal price of canned tuna, for example, declined from $2.55 in 1980 to $1.78 in 2004. Between 1979 and 2003, the real or deflated (2004 constant dollar value) ex-vessel price of all finfish and shellfish combined declined from $0.76 to $0.35 per pound. The domestic seafood industry is experiencing problems in the form of competition from imports and increased fuel prices, and established generic marketing programs have been shown to be effective in improving the demand for some food commodities. The RIR analysis summarized below indicates that similar marketing programs, if effective in raising prices, could generate positive net benefits and provide for increased national economic impacts.

The economic analysis performed in support of this action examined 12 species complexes: (1) Grouper (all species of group), (2) snapper (all species of snapper), (3) roundfish (cod, haddock, and pollock), (4) tuna (all species of tuna), (5) halibut, (6) flatfish (all species of flatfish), (7) salmon (all wild caught species of salmon), (8) scallops (all species of scallops), (9) Dungeness and snow crab, (10) all other species of crabs, (11) lobster (spiny and North American), and (12) all species of shrimp. Per capita consumption was defined as per-capita landings between 1950 and 2003. A synthetic inverse demand system (SIDS) model was specified and estimated following Park et al. (2004). The SIDS model was used to estimate changes in ex-vessel revenues and compensating variation or economic value, which might be induced by a successful generic marketing program. Economic impacts were estimated using a national input/output model, which was developed for NOAA Fisheries in 2004. The estimation of impacts also did not include the potential impacts of other

meat producing and consuming sectors (e.g., cattle producers and consumers of beef).

Based on the potential changes in sales of Alaska's, Maryland's, and the Tilapia Marketing Association's marketing campaigns for salmon, blue crabs, and tilapia, the analysis of economic impact prepared by NMFS assumed that a marketing campaign could promote a 10 percent increase in demand. These relatively small, homogeneous groups with common goals were successful in reaching agreement on developing a marketing strategy. During the Alaskan salmon campaign, sales (quantity demanded) increased by 19.6 percent; sales of blue crabs in Maryland increased by 52.2 percent; and sales of Tilapia increased by more than 54.5 percent between 2001 and 2003. As much as 40% of Alaskan salmon wild landings are based on hatchery production and tilapia is a fresh water aquaculture product; both products can be increased to respond to increases in demand. Maryland blue crab while a substantial part is still only a single component of a much larger market allowing for the reallocation of sales between different markets due to real or perceived quality differences. Larger, heterogeneous groups with different goals and objectives could have substantially higher costs of reaching agreement on a marketing strategy; preventing an effective strategy from being developed. The Federal government can assist in reducing these costs, but its involvement must be limited in these TAC-limited, marine, wild-capture fisheries to the extent that an increase in demand would not jeopardize conservation goals and objectives.

NOAA stewardship of fisheries resources under the Magnuson-Stevens Act, Endangered Species Act, and other applicable laws in managing U.S. fisheries ensures that conservation and management goals and objectives are not jeopardized. As part of this process, NMFS must submit annually a Status of Fisheries Stocks report to Congress reporting on the status of overfished fisheries and fisheries where overfishing is continuing. Seafood Council actions established under this rule may not interfere with the continued management and conservation of fisheries required under other statutes.

The analysis estimated potential changes in revenues and welfare and was limiting since: it considered only the harvesting sector; the processing and final retail sectors were not included; the analysis considered a marketing program, which increased the per capita quantity demanded; no attention was given to whether or not a marketing program would shift out the demand or change the various quantity coefficients, which would be an expected effect of a marketing campaign. Alternatively, a marketing program would be expected to increase the demand for a given price, and thus, shift the demand curve out from the origin so that at every price, consumers would demand more seafood. Without detailed information on the relationship between advertising and seafood demand, it is difficult to even state the magnitude of bias from assuming that a marketing program increases the quantity demanded.

As illustrated in Tables 1, a 10 percent increase in the demand for seafood generates considerable economic activity for the U.S. economy. If the demand for all 12 species or species grouping were to increase by 10 percent (or $108.1 million ex-vessel), this would, in turn, generate total sales of $500.7 million in the U.S. economy and $172.3 million in income (which includes profits). Those species with the potential greatest level of economic impacts are shrimp, salmon, and tuna. Combined, they account for nearly 60 percent of the total potential output, 58 percent of the total potential income, and 59 percent of the total potential employment.

TABLE 1. CHANGES IN OUTPUT (1,000$ OF 2004 CONSTANT DOLLARS) GENERATED BY A 10% INCREASE IN THE DEMAND FOR SEAFOOD

Harvesting Sector		Harvesting Sector Impacts				Processor, Wholesaler, and Dealer Impacts				Impacts for All Sectors			
Species	Change In Ex-vessel Revenues	Direct	Indirect	Induced	Total	Direct	Indirect	Induced	Total	Direct	Indirect	Induced	Total
Grouper	561.1	335	228	745	1,308	389	272	871	1,532	724	500	1,616	2,840
Snapper	1,391.3	830	566	1,846	3,242	966	673	2,159	3,797	1,796	1,239	4,005	7,040
Roundfish	8,018.8	4,088	2,840	11,204	18,132	5,569	3,876	12,442	21,887	9,657	6,716	23,646	40,019
Tuna	15,920.5	10,135	6,956	14,519	31,610	9,966	7,899	25,399	43,264	20,101	14,855	39,918	74,874
Salmon	23,620.2	17,173	12,499	27,314	56,985	16,404	11,418	36,650	64,473	33,577	23,917	63,964	121,458
Halibut	3,555.7	2,045	1,445	4,777	8,267	2,469	1,719	5,517	9,705	4,514	3,164	10,294	17,972
Flatfish	6,518.5	3,891	2,808	8,563	15,262	4,447	3,166	10,165	17,778	8,338	5,974	18,728	33,040
Sea Scallop	3,362.6	1,991	1,576	4,380	7,947	2,335	1,625	5,217	9,178	4,326	3,202	9,597	17,125
Dungeness and Snow Crab	2,995.3	2,102	1,338	3,737	7,178	2,080	1,448	4,647	8,176	4,182	2,786	8,385	15,353
All Other Crabs	10,984.6	7,709	4,908	13,706	26,332	7,629	5,310	17,043	29,981	15,338	10,218	30,749	56,313
Lobster	2,393.1	1,875	1,456	2,678	6,009	1,221	1,239	3,995	6,455	3,096	2,695	6,674	12,464
Shrimp	28,756.5	19,681	15,987	32,489	68,157	8,450	5,916	19,631	33,998	28,131	21,903	52,120	102,155
Total harvesters	108,078.2	71,853	52,607	125,960	250,430	61,927	44,561	143,736	250,223	133,781	97,169	269,696	500,653

A generic marketing campaign, if successful, would be expected to increase sales of seafood. Using the estimated changes in revenues associated with a generic marketing campaign, which is assumed to generate at least a 10 percent increase in sales, and the national I/O model, changes in output or sales and income are estimated. The analysis, however, ignores potential changes in other sectors of the economy, which might result from increased sales in seafood (e.g., the impacts on beef, pork, and poultry producers and processors). The impacts do, however, explicitly consider changes in demand from supporting or related seafood sectors (e.g., fuel and gear for vessels, purchases of supplies by processors, etc.).

It was estimated that a successful generic commodity program for all 12 species could generate up to $108.1 million (2004 constant dollar value) in addition ex-vessel revenues, and $115.5 million in consumer welfare or compensating variation; i.e., net benefits. The largest gains were determined to be associated with shrimp, salmon, and tuna. In terms of the potential changes in economic impacts, it was estimated that generic commodity programs for the 12 species or species groupings could increase sales and income by, respectively, $500.7 million and $172.3 million. Shrimp, salmon, and tuna were determined to be the largest beneficiaries of generic commodity programs, which successfully increased consumption by 10 percent. In addition to the limitations already discussed, the analysis excludes the costs of generic commodity programs. Existing programs in the U.S., regardless of whether or not the program promotes seafood or beef, pork, or poultry, typically impose charges on producing and/or marketing companies. These costs, if known, would have to be deducted from the estimated benefits.

The analysis also does not consider the distribution of potential benefits or economic welfare; that is, it remains unknown whether or not a generic commodity program would benefit fishers, processors and dealers, retailers, all, or one group more than the other. The analysis also does not consider the possibility that generic commodity programs will potentially benefit importers and foreign producers of seafood. Most U.S. fisheries are heavily regulated, and there has been an increasing reliance on imports, and thus, it is unlikely that in the near future, domestic producers would be able to satisfy an increased demand for seafood. Alternatively, a generic commodity program, which resulted in increased supplies of imports, could drive domestic ex-vessel and retail prices down. Producers would experience declining revenues and profits, but consumers might experience increased welfare. Although the RIR indicates that the potential exists for the generation of positive net benefits from a marketing program, the merits of a specific proposed council would have to be judged on a case by case basis.

Unfortunately, data necessary for conducting an economic analysis of the potential benefits and impacts of generic marketing campaigns or generic commodity programs are not available. There is insufficient information to statistically examine the relationship between advertising expenditures for seafood and the demand for seafood. Data are not available on retail prices and consumption, by species, or mode of sale (e.g., fish markets, grocery stores, and restaurants). Cost and earnings data are highly inconsistent over time, and thus it is not possible to consider returns to the various producing and marketing sectors--harvesters, processors, wholesalers, retail outlets, and restaurants. Moreover, no seafood entity has yet proposed a generic commodity program.

A review of the scant empirical data available on generic commodity programs reveals mixed evidence about the success of generic marketing campaigns, particularly relative to seafood. One study suggests that generic advertising to promote the sales of seafood either had no effect on sales or depressed sales. Another study concluded that advertising and health awareness significantly affected the demand for seafood; these studies, however, were restricted to one retail firm in Houston, and used inches of print in fliers and newspapers as a measure of advertising. The Alaska Seafood Marketing Institute (ASMI), the Maryland Seafood Marketing Advisory Commission, and the Tilapia Marketing Institute have stated that they implemented successful marketing campaigns, respectively, for salmon, blue crabs, and tilapia. Up to 40 percent of the wild-capture, Alaskan salmon starts its life in hatcheries and tilapia is a product of fresh-water aquculture product, both of which can be increased in supply to match market pressures. Per capita consumption of tilapia increased by nearly 55.0 percent between 2001 and 2003; they initiated the marketing campaign in 1999. Total landings of Alaskan salmon increased 21.8 percent between 2001 and 2002; the years the ASMI conducted a generic marketing program for salmon. Maryland blue crab, on the other hand, is a wild-capture fishery that needs to be carefully monitored to ensure that overfishing does not occur. Large increases in sales were also found to characterize Maryland blue crabs following their implementation of a marketing program for blue crabs. While a significant part, Maryland blue crab landings are only a portion of the total fishery and these increases in landings could represent a reallocation of demand from one segment of the market to another in response to changes in perceived product quality. While promotional programs involving homogeneous and species-specific products have been for the most part successful, an attempt to form a national seafood Council to promote an increase in consumption of all seafood failed because of difficulty in getting agreement among fishermen, processors, and marketing firms over funding, program thrusts, and other elements required to make a program successful. In addition, increases in generic seafood demand in times prior to the large scale availability of imported seafood products created concerns among managers that increased prices at the dockside might create additional harvesting pressure for already overexploited fish stocks.

While data are not available to measure the direct effects of advertising on seafood demand, over the last two decades agricultural economists have estimated rates of return from promotional programs under the Department of Agriculture's checkoff programs developed for beef, pork, and soybeans. In a checkoff program, producers are required to pay a fee based on a fraction of their production to commodity marketing and development boards. The fees are used to promote consumption and support production and utilization research. A 2000 study to measure effects of the pork checkoff program on demand estimated returns to advertising investment as measured by a net benefit cost ratio (NBCR) to be 15 to 1, while in 2001, the NBCR for advertisement and research investment for soybeans was estimated at 8 to 1. These large benefit to cost ratios need to be tempered when applied to fishery products because agricultural product supplies can be increased when prices rise creating additional benefits in the form of producer and consumer surplus. Fish product supplies are generally fixed by regulation and increases in prices can cause the dissipation of rents in a command and control managed fishery. In a rationalized fishery, such as

halibut/sablefish or wreck fish, such rent dissipation would not occur and net benefits could increase substantially as was demonstrated in recent studies of proposed rationalization programs for the Gulf of Mexico shrimp fishery.

Potential Economic Impact to Small Entities

Agricultural commodity promotional programs have yielded aggregate profitability of varying degrees as measured by several studies using econometric techniques. Furthermore, as indicated through referenda for beef, poultry, and pork, agricultural producers have in large part supported checkoff programs in their respective commodities. The few studies involving seafood marketing programs indicate that they have been, for the most part, successful when involving a specific product. Based on the results of these studies NMFS has concluded that marketing boards that are species and or product specific are likely to be successful in increasing demand and, hence, profitability for the sector or sectors of the fishery represented by the Council. Therefore, small entities, on average, would likely profit, at least in the short term, from a well-run and managed Council. While the typical fishery may profit from increased demand through advertising and other promotions, there would be no guarantee that all fisheries and all sectors of fisheries and the firms comprising those sectors would profit equally. This would depend on individual firm's profit margins, the assessment fee, and price effects caused by advertising (positive) and the ability of non-participants to profit from free advertising (negative) by increasing supply and driving down prices (also known as the free rider problem). There is also the mandatory versus voluntary participation or the ''under-advertising'' argument.

Profit Margins

NMFS recognizes that profit margins will vary largely by fishery sector and individual firms within fishery sectors. There are examples of small firms with larger profit margins within a fishery or sector of a fishery than their larger counterparts, e.g., small-vessel groundfish harvesters in the Northeast. Producers of specialty products for niche markets such as fancy canned albacore, smoked mussels, shrimp cocktail, etc. are assumed to have higher profit margins than their large volume counterparts. Nevertheless, direct impacts to the profit margins of individual firms from seafood marketing programs would depend on the increase in gross receipts attributable a Council's marketing efforts versus the amount of fees they are assessed. Increased demand would increase revenues to the aggregate of firms comprising any one market, but this does not guarantee that individual firms would have similar increases in gross receipts measured in magnitude or as a percentage of the total increase. Therefore, there could be marginal firms whose profit margins are smaller than the representative sector that would not benefit greatly from an increased demand yet be saddled with an assessment fee. The number of these firms, if they exist, is indeterminate. However, it is unlikely that business failures would occur as a result of creating a Council.

Assessment Fees

Assessment fees exacted by agriculture marketing programs have a commonality in that the fees are based on relative levels of production, e.g., the fees for the dairy, soybean, and beef marketing programs are 2 cents per gallon, 0.5 percent of sales price, and 1 dollar per head of live weight, respectively. This rule would implement a fee similar to those specified for agriculture programs based on a percentage or a fixed amount per unit of weight or volume based on gross sales receipts for producers or product costs for importers. Either way, these methods of imposing fees should minimize any disproportionate impacts on profitability for small firms versus large firms from the assessment of fees within fisheries or sectors of fisheries. If the fee were not based on a relative assessment, small firms could be negatively impacted by large blanket fees. This rule would allow individual firms to request and collect a refund of fees ninety-days after an assessment. The methods and the timing of refunds would need to be specified in a Council's charter.

Price Effects and the Free Rider Problem

The magnitudes of price changes relative to increased demand or supply depend on price elasticities of demand or supply in a given product market. With the exception of a few species of seafood, most notably American lobster, seafood markets exhibit an elastic or flat demand and an inelastic supply because many substitute commodities exist for fishery products. As a result, prices would remain relatively stable with large increases in fishery products supplies. With relatively fixed supplies of fish, at least in the short run, changes in seafood demand could result in large changes in price. Therefore, an increase in demand would most likely exhibit relatively higher returns to individual and aggregate firms than agricultural firms. The ''free rider'' problem would occur if a demand induced increase in price caused by a marketing program triggers an appreciable amount of supply onto the market from non-participants, i.e., entities who paid no fee for the promotion of the product but benefitted from the marketing campaign. The use of quality seals or ecolabels such as ''dolphin free'' tuna create easily identifiable quality differences between essentially homogeneous products and prevent the ''free rider'' problem from occurring and the associated dissipation of benefits generated by the initial marketing efforts. As a result, if the ''free rider'' problem did exist for fishery products, it would likely not be as severe as the situation facing other commodity markets since domestic supplies are relatively fixed under the present management regime and the creation of seals or labels would, in most cases, create a differentiated product for consumers in domestic markets.

Voluntary Versus Mandatory Participation

Agricultural marketing programs conceived under various legislation incorporate mandatory participation programs based on the economic premise that -- if the majority of potential participants accept, through referenda, the idea that additional profits could be earned through a marketing program, then it would be profitable for all firms to participate. The economic reality faced by the agricultural marketing programs is that if only the firms voting in the affirmative in a given referendum were subject to assessment there might not be enough operating funds to carry out the mandates of the legislation imposed, i.e., increase wealth by increasing demand and/or introducing better products. If NMFS, through its authority to waive fees, did not impose mandatory participation in a particular Council, i.e., voluntary participation, it is safe to assume that those firms voting in the affirmative in a referendum had determined a priori that it would be economically advantageous to pay an assessment fee through a Council to promote their products. Therefore, it would be difficult to make the case that implementation of a voluntary Council would have adverse impacts on those participants who voted in the affirmative. However, a voluntary program would face two obstacles. Firstly, there could be a level of funding through voluntary assessments that would not allow a Council to create a

promotional program that would meet the objective of increasing demand for a particular product(s). Secondly, the level of funding may not be optimal to achieve maximum benefits of a marketing program. In the case of voluntary participation, fisheries, in general, would be less affected by the free rider problem when compared to other commodity markets due to the different price elasticities of demand and supply, use of labels and quality standards, and the regulatory control of supplies.

Paper Work Reduction Act

This proposed rule contains a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been submitted to OMB for approval. The information collection requirements contained in this rule can be broadly categorized into two categories: (1) Information required of an individual or organization applying for consideration to form a Council, and (2) information required of a formed and operating Council. Information required of an individual or organization applying for consideration to form a Council, consists of an ''application for charter'' that is composed of three sections: petition, proposed charter, and a list of eligible referendum participants. Based on discussions with the tuna industry, (the seafood industry group most likely to first apply for formation of a Council), the estimated reporting time for this portion of the collection requirement in 50 CFR 270 is 320 hours in total, with an average of 80 hours to develop a petition, 200 hours to develop a proposed charter, and 40 hours to develop a list of eligible referendum participants. All other information requirements in the proposed rule are imposed on the Councils, once they are established. The estimated reporting time for these information requirements varies from 1 to 120 hours per response. Council submission of an annual plan, an annual budget, and an annual financial report are estimated at 120 hours each for a total of 360 hours. Council submissions of semi-annual progress reports is estimated at 40 hours twice a year, notice of assessments at 20 hours once a year, list of Council nominations following a favorable referendum at 20 hours once a year, and meeting notices at 1–2 hours once a year. Other submissions are optional and are dependent upon the operation of a particular Council and its participants. For instance, Council submission of a plan to conduct a referendum on development of quality standards is estimated at 40 hours with no more than annual frequency. Additionally, assessed participants of a Council submission of a petition of objection and/or request for refund is estimated at 2 hours each no more than 6 times a year. These estimated reporting times include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to NMFS and OMB (see **ADDRESSES**).

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection-of-information displays a currently valid OMB control number.

List of Subjects in 50 CFR Part 270

Administrative practice and procedure, Fish, Marketing, Seafood.

Dated: January 17, 2006.

William T. Hogarth,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS proposes to amend title 50 chapter II as follows:

1. A new subchapter H consisting of part 270 is added to read as follows:

SUBCHAPTER H—FISH AND SEAFOOD PROMOTION

PART 270—SPECIES-SPECIFIC SEAFOOD MARKETING COUNCILS

Sec.

§ 270.1 Scope.
§ 270.2 Definitions.
§ 270.3 Submission of application.
§ 270.4 Review of application.
§ 270.5 Conduct of referendum.
§ 270.6 Sector participants eligible to vote.
§ 270.7 Results of referendum.
§ 270.8 Nomination and appointment of Council members.
§ 270.9 Terms, vacancies, and removal of Council members.
§ 270.10 Responsibilities of a Council.
§ 270.11 Responsibilities of NMFS.
§ 270.12 Notice of Council meetings.
§ 270.13 Books, records and reports.
§ 270.14 Update of sector participant data.
§ 270.15 Quality standards.
§ 270.16 Deposit of funds.
§ 270.17 Authority to impose assessments.
§ 270.18 Method of imposing assessments.
§ 270.19 Notice of assessment.
§ 270.20 Payment of assessments.
§ 270.21 Petition of objection.
§ 270.22 Refunds.
§ 270.23 Dissolution of Councils.

Authority: 16 U.S.C. 4001–4017.

§ 270.1 Scope.

This part 270 describes matters pertaining to the establishment, representation, organization, practices, procedures, and termination of Seafood Marketing Councils.

§ 270.2 Definitions.

The following terms and definitions are in addition to or amplify those contained in the Fish and Seafood Promotion Act of 1986:

Act means the Fish and Seafood Promotion Act of 1986 (Pub. L. 99–659) and any subsequent amendments.

Consumer education means actions undertaken to inform consumers of matters related to the consumption of fish and fish products.

Council means a Seafood Marketing Council for one or more species of fish and fish products of that species established under section 210 of the Act (16 U.S.C. 4009).

Expenditure means monetary or material worth of fishery products. Expenditure is determined at the point a receiver obtains product from a harvester or an importer obtains product from a foreign supplier. Value may be expressed in monetary units (the price a receiver pays to a harvester or an importer pays to a foreign supplier).

Fiscal year means any 12-month period as NMFS may determine for each Council.

Fish means finfish, mollusks, crustaceans, and all other forms of aquatic animal life used for human consumption; the term does not include marine mammals and seabirds.

Harvester means any person in the business of catching or growing fish for purposes of sale in domestic or foreign markets.

Importer means any person in the business of importing fish or fish products from another country into the United States and its territories, as defined by the Act, for commercial purposes, or who acts as an agent, broker, or consignee for any person or

nation that produces, processes or markets fish or fish products outside of the United States for sale or for other commercial purposes in the United States.

Marketer means any person in the business of selling fish or fish products in the wholesale, export, retail, or restaurant trade, but whose primary business function is not the processing or packaging of fish or fish products in preparation for sale.

Marketing and promotion means any activity aimed at encouraging the consumption of fish or fish products or expanding or maintaining commercial markets for fish or fish products.

Member means any person serving on any Council.

Participant means a member of a sector or business identified in an application for a Council charter as being subject to the referendum or assessment process.

Person means any individual, group of individuals, association, proprietorship, partnership, corporation, cooperative, or any private entity of the U.S. fishing industry organized or existing under the laws of the United States or any state, commonwealth, territory or possession of the United States who meets the eligibility requirements as defined in a proposed charter to vote in a referendum.

Processor means any person in the business of preparing or packaging fish or fish products (including fish of the processor's own harvesting) for sale in domestic or foreign markets.

Receiver means any person who owns fish processing vessels and any person in the business of acquiring (taking title to) fish directly from harvesters.

Research means any type of research designed to advance the image, desirability, usage, marketability, production, quality and safety of fish and fish products.

Secretary means the Secretary of Commerce, or the Secretary's designee.

Sector means

(1) The sector consisting of harvesters;

(2) The sector consisting of importers;

(3) The sector consisting of marketers;

(4) The sector consisting of processors;

(5) The sector consisting of receivers; or

(6) The consumer sector consisting of persons professionally engaged in the dissemination of information pertaining to the nutritional benefits and preparation of fish and fish products;

Sector participant means any individual, group of individuals, association, proprietorship, partnership, corporation, cooperative, or any private entity of the U.S. fishing industry organized or existing under the laws of the United States or any state, commonwealth, territory or possession of the United States who meets the eligibility requirements as defined in a proposed charter to vote in a referendum.

Species means a fundamental category of taxonomic classification, ranking after genus, and consisting of animals that possess common characteristic(s) distinguishing them from other similar groups.

Value means monetary or material worth of fishery products. Value is the difference between what a receiver is willing to pay for a product provided by a harvester and its market price or an importer is willing to pay for a product from a foreign supplier and its market price. Value may be expressed in monetary units representing consumer surplus or producer surplus.

§ 270.3 Submission of application.

(a) Persons who meet the minimum requirements for sector participants as described in the proposed charter may file an application with NMFS for a charter for a Seafood Marketing Council for one or more species of fish and fish products of that species. One signed original and two copies of the completed application package must be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, NOAA, 1315 East-West Highway, Silver Spring, Maryland 20910. Applications should not be bound.

(b) The application consists of four parts:

(1) A document requesting NMFS to establish a Council;

(2) A proposed charter under which the proposed Council will operate;

(3) A list of eligible referendum participants; and

(4) Analytical documentation addressing requirements of applicable law.

(c) *Content of application*—(1) *Application or requesting document.* The application or requesting document submitted by the applicants to NMFS requesting that the Council be established, to the extent practicable, must include the signatures or corporate certifications, of no less than three sector participants representing each sector identified in accordance with paragraph (c)(2)(v) of this section and who, according to the available data, collectively accounted for, in the 12-month period immediately preceding the month in which the application was filed, not less than 10 percent of the value of the fish or fish products specified in the charter that were handled during such period in each sector by those who meet the eligibility requirements to vote in the referendum as defined by the application. The application must also include a statement that, if established, the Council will have sufficient resources (e.g., cash, donated office space, services, supplies, etc.) available for initial administrative expenditures pending collection of assessments.

(2) *Proposed charter.* A proposed charter must contain, at a minimum, the following information:

(i) The name of the Council and a provision proclaiming its establishment;

(ii) A declaration of the purposes and objectives of the Council;

(iii) A description of the species of fish and fish products, including the scientific and common name(s), for which the Council will implement marketing and promotion plans under the Act. (The American Fisheries Society's ''List of Common and Scientific Names of Fishes from the United States and Canada'' (latest edition) or where available, an appropriate volume of its ''List of Common and Scientific Names of Aquatic Invertebrates of the United States and Canada'' (latest edition) should be used as the authority for all scientific and common names.);

(iv) A description of the geographic area (state(s)) within the United States covered by the Council;

(v) The identification of each sector and the number and terms of representatives for each sector that will be voting members on the Council. (The number of Council members should be manageable, while ensuring equitable geographic representation. The term for members will be 3 years. Initially, to ensure continuity, half of the members' terms will be 2 years and half will be 3 years. Reappointments are permissible.);

(vi) The identification of those sectors (which must include a sector consisting of harvesters, a sector consisting of receivers, and, if subject to assessment, a sector consisting of importers), eligible to vote in the referendum to establish the Council;

(vii) For each sector described under paragraph (c)(2)(v) of this section, a threshold level specifying the minimum requirements, as measured by income, volume of sales, or other relevant factors, that a person engaging in business in the sector must meet in order to participate in a referendum;

(viii) A description of the rationale and procedures for determining assessment rates as provided in § 270.18, based on a fixed amount per

unit of weight or measure, or on a percentage of value of the product handled;

(ix) The proposed rate or rates that will be imposed by the Council on receivers and, if subject to assessment, importers during its first year of operation;

(x) The maximum amount by which an assessment rate for any period may be raised above the rate applicable for the immediately preceding period;

(xi) The maximum rate or rates that can be imposed by a Council on receivers or importers during the operation of the Council;

(xii) The maximum limit on the amount any one sector participant may be required to pay under an assessment for any period;

(xiii) The procedures for providing refunds to sector participants subject to assessment who request the same in accordance with the time limits specified § 270.22;

(xiv) A provision setting forth the voting procedures by which votes may be cast by proxy;

(xv) A provision that the Council will have voting members representing the harvesting, receiving and, if subject to assessment, importing sectors;

(xvi) A provision setting forth the definition of a quorum for making decisions on Council business and the procedures for selecting a chairperson of the Council;

(xvii) A provision that members of the Council will serve without compensation, but will be reimbursed for reasonable expenses incurred in performing their duties as members of the Council;

(xviii) A provision containing a requirement for submission to NMFS the criteria and supporting data for evaluating the annual and/or multi-year performance of proposed marketing plans and the Council's performance;

(xix) A provision containing a requirement for submission of documentation as requested by NMFS for purposes of evaluating performance of proposed marking plans and the Council's related performance;

(xx) Where adequate funds are not available, a provision containing the minimum number of participants needed for sustained operations that cannot receive assessment refunds;

(xxi) A provision acknowledging that NMFS will have the right to participate in Council meetings;

(xxii) A provision that the Council will conduct its activities in accordance with applicable NMFS requirements and that NMFS has final approval authority over proposed marketing plans and Council actions;

(xxiii) A provision containing a requirement for the Council to arrange for a complete audit report to be conducted by an independent public accountant and submitted to NMFS at the end of each fiscal year;

(xxiv) A provision containing a requirement for the Council to conduct a market assessment based on economic, market, social and demographic, and biological information as deemed necessary by NMFS; and

(xxv) A provision containing a requirement for the Council to update the list of referendum participants on an annual basis.

(3) *List of referendum participants.* The list of referendum participants, to the extent practicable, must identify the business name and address of all sector participants that the applicants believe meet the requirements for eligibility to vote in the referendum on the adoption of the proposed charter.

(i) The list should include all sectors in which a sector participant meets the eligibility requirements to vote in a referendum. If a sector participant has more than one place of business located within the geographic area of the Council, all such places should be listed and the primary place of business should be designated. The agency will provide appropriate information in its possession of a non-proprietary nature to assist the applicants in developing the list of sector participants.

(ii) [Reserved]

(4) *Analytical documentation.* The applicant must address the requirements of the Act, implementing regulations, and other applicable law, i.e., E.O. 12866, Regulatory Flexibility Act, National Environmental Policy Act, and other law as NMFS determines appropriate.

§ 270.4 Review of application.

Within 180 days of receipt of the application to establish a Council, NMFS will:

(a) Determine if the application is complete and complies with all of the requirements set out in § 270.3 and complies with all provisions of the Act and other applicable laws.

(b) Identify, to the extent practicable, those sector participants who meet the requirements for eligibility to participate in the referendum to establish the Council. NMFS may require additional information from the applicants or proposed participants in order to verify eligibility. NMFS may add names to or delete names from the list of sector participants believed eligible by the applicants until the time of the referendum based on additional information received.

(c) If NMFS finds minor deficiencies in an application that can be corrected within the 180-day review period, NMFS will advise the applicants in writing of what must be submitted by a specific date to correct the minor deficiencies.

(d) If NMFS makes a final negative determination, on an application, NMFS will advise the applicant in writing of the reason for the determination. The applicant may submit another application at any time thereafter. NMFS then has 180 days from receipt of the new application to render a final determination on its acceptability.

§ 270.5 Conduct of referendum.

(a) Upon making affirmative determinations under § 270.4, NMFS, within 90 days after the date of the last affirmative determination, will conduct a referendum on the adoption of the proposed charter.

(b) NMFS will estimate the cost of conducting the referendum, notify the applicants, and request that applicants post a bond or provide other applicable security, such as a cashier's check, to cover costs of the referendum.

(c) NMFS will initially pay all costs of a referendum to establish a Council. Within two years after establishment, the Council must reimburse NMFS for the total actual costs of the referendum from assessments collected by the Council. If a referendum fails to result in establishment of a Council, NMFS will immediately recover all expenses incurred for conducting the referendum from the bond or security posted by applicants. In either case, such expenses will not include salaries of government employees or other administrative overhead, but will be limited to those additional direct costs incurred in connection with conducting the referendum.

(d) No less than 30 days prior to holding a referendum, NMFS will:

(1) Publish in the **Federal Register** the text of the proposed charter and the most complete list available of sector participants eligible to vote in the referendum; and

(2) Provide for public comment, including the opportunity for a public meeting.

§ 270.6 Sector participants eligible to vote.

(a) Any participant who meets the minimum requirements as measured by income, volume of sales or other relevant factors specified in the approved charter may vote in a referendum.

(b) Only one vote may be cast by each participant who is eligible to vote, regardless of the number of individuals

that make up such ''participant'' and how many sectors the participant is engaged in. The vote may be made by any responsible officer, owner, or employee representing a participant.

§ 270.7 Results of referendum.

(a) *Favorable vote to establish a Council.* NMFS will, by order, establish the Council and approve an acceptable proposed charter, if the referendum votes which are cast in favor of the proposed charter constitute a majority of the sector participants voting in each and every sector. Further, according to the best available data, the majority must collectively account for, in the 12-month period immediately preceding the month in which the proposed charter was filed, at least 66 percent of the value of the fish and fish products described in the proposed charter handled during such period in each sector by those who meet the eligibility requirements to vote in the referendum as defined by the applicants.

(b) *Unfavorable vote to establish a Council.* If a referendum fails to pass in any sector of the proposed Council, NMFS will not establish the Council or approve the proposed charter. NMFS will immediately recover the cost of conducting the referendum according to § 270.5(c).

(c) *Notification of referendum results.* NMFS will notify the applicants of the results of the referendum and publish the results of the referendum in the **Federal Register**.

§ 270.8 Nomination and appointment of Council members.

(a) Within 30 days after a Council is established, NMFS will solicit nominations for Council members from the sectors represented on the Council in accordance with the approved charter. If the harvesters and receivers represented on the Council are engaged in business in two or more states, but within the geographic area of the Council, the nominations made under this section must, to the extent practicable, result in equitable representation for those states. Nominees must be knowledgeable and experienced with regard to the activities of, or have been actively engaged in the business of, the sector that such person will represent on the Council. Therefore, a resume will be required for each nominee.

(b) In accordance with 16 U.S.C. 4009(f), NMFS will, within 60 days after the end of the 30-day period, appoint the members of the Council from among the nominees.

§ 270.9 Terms, vacancies and removal of Council members.

(a) A Council term is for 3 years, except for initial appointments to a newly established Council where:

(1) Half of the Council member terms will be 2 years; and

(2) Half of the Council member terms will be 3 years.

(b) A vacancy on a Council will be filled, within 60 days after the vacancy occurs, in the same manner in which the original appointment was made. A member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed will be appointed only for the remainder of such term.

(c) Any person appointed under the Act who consistently fails or refuses to perform his or her duties properly and/or participates in acts of dishonesty or willful misconduct with respect to responsibilities under the Act will be removed from the Council by NMFS if two-thirds of the members of the Council recommend action. All requests from a Council to NMFS for removal of a Council member must be in writing and accompanied by a statement of the reasons upon which the recommendation is based.

§ 270.10 Responsibilities of a Council.

(a) Each Council will:

(1) Implement all terms of its approved charter;

(2) Prepare and submit to NMFS, for review and approval under § 270.11(a)(1), a marketing and promotion plan and amendments to the plan which contain descriptions of the projected consumer education, research, and other marketing and promotion activities of the Council;

(3) Implement and administer an approved marketing and promotion plan and amendments to the plan;

(4) Determine the assessment to be made under § 270.18 and administer the collection of such assessments to finance Council expenses described in paragraph (b) of this section;

(5) Receive, investigate and report to NMFS accounts of violations of rules or orders relating to assessments collected under § 270.20, or quality standard requirements established under § 270.15;

(6) Prepare and submit to NMFS, for review and approval a budget (on a fiscal year basis) of the anticipated expenses and disbursements of the Council, including

(i) All administrative and contractual expenses;

(ii) The probable costs of consumer education, research, and other marketing and promotion plans or projects;

(iii) The costs of the collection of assessments; and

(iv) The expense of repayment of the costs of each referendum conducted in regard to the Council.

(7) Comply with NMFS requirements, and prepare and submit to NMFS for review, evaluation, and verification of results and analysis an annual market assessment and related analytical documentation that is based on economic, market, social, demographic, and biological information as deemed necessary by NMFS;

(8) Maintain books and records, prepare and submit to NMFS reports in accordance with respect to the receipt and disbursement of funds entrusted to it, and submit to NMFS a completed audit report conducted by an independent auditor at the end of each fiscal year;

(9) Reimburse NMFS for the expenses incurred for the conduct of the referendum to establish the Council or any subsequent referendum to terminate the Council that fails;

(10) Prepare and submit to NMFS report or proposals as the Council determines appropriate to further the purposes of the Act.

(b) Funds collected by a Council under § 270.17 will be used by the Council for--

(1) Research, consumer education, and other marketing and promotion activities regarding the quality and marketing of fish and fish projects;

(2) Other expenses, as described in § 270.10(a)(1);

(3) Such other expenses for the administration, maintenance, and functioning of the Council as may be authorized by NMFS; and

(4) Any reserve fund established under § 270.10(e)(4) of this section and any administrative expenses incurred by NMFS specified as reimbursable under this Part.

(c) Marketing and promotion plans and amendments to such plans prepared by a Council under § 270.10(a)(2) of this section will be designed to increase the general demand for fish and fish products described in accordance with § 270.3(c)(2)(iii) by encouraging, expanding, and improving the marketing, promotion and utilization of such fish and fish products, in domestic or foreign markets, or both, through consumer education, research, and other marketing and promotion activities.

(d) Consumer education and other marketing and promotion activities carried out by a Council under a marketing and promotion plan and amendments to a plan may not contain

references to any private brand or trade name and will avoid the use of deceptive acts or practices in promoting fish or fish products or with respect to the quality, value, or use of any competing product or group of products.

(e) *Authority of a Council.* A Council may:

(1) Sue and be sued;

(2) Enter into contracts;

(3) Employ and determine the salary of an executive director who may, with the approval of the Council employ and determine the salary of such additional staff as may be necessary;

(4) Establish a reserve fund from monies collected and received under § 270.17 to permit an effective and sustained program of research, consumer education, and other marketing and promotion activities regarding the quality and marketing of fish and fish products in years when production and assessment income may be reduced, but the total reserve fund may not exceed the amount budgeted for the current fiscal year of operation.

(f) *Amendment of a charter.* A Council may submit to NMFS amendments to the text of the Council's charter. Any proposed amendments to a charter will be approved or disapproved in the same manner as the original charter was approved under § 270.4 and § 270.5 with the exception of § 270.4(b).

§ 270.11 Responsibilities of NMFS.

(a) In addition to the duties prescribed under 16 U.S.C. 4009, NMFS will:

(1) Participate in Council meetings and review, for consistency with the provisions of 50 CFR 270 and other applicable law, and approve or disapprove, marketing and promotion plans and budgets within 60 days after their submission by a Council;

(2) Immediately notify a Council in writing of the disapproval of a marketing and promotion plan or budget, together with reasons for such disapproval;

(3) Issue orders and amendments to such orders that are necessary to implement quality

standards under § 270.15;

(4) Promulgate regulations necessary to carry out the purposes of this chapter;

(5) Enforce the provisions of the Act;

(6) Make all appointments to Councils in accordance with § 270.8 and the approved Council charter;

(7) Approve the criteria and time frames under which a Council's performance will be evaluated; and

(8) Implement the provisions of 16 U.S.C. 4001 *et seq.* in accordance with the available financial and management resources NMFS determines can be utilized.

(b) NMFS may provide, on a reimbursable or other basis, such administrative or technical assistance as a Council may request for purposes of the initial organization and subsequent operation of the Council. However, a Council is responsible for the cost of preparing and submitting information (e.g., reports, evaluation data, etc.) requested by NMFS.

§ 270.12 Notice of Council meetings.

The Council will give NMFS the same notice of its meetings as it gives to its members. NMFS will have the right to participate in all Council meetings.

§ 270.13 Books, records and reports.

(a) The Council must submit to NMFS the following documents according to the schedule approved in the Council's charter:

(1) A marketing assessment and promotion plan;

(2) A financial report with respect to the receipt and disbursement of funds;

(3) An audit report conducted by an independent public accountant; and

(4) Other reports or data NMFS determines necessary to evaluate the Council's performance and verify the results of the market assessment and promotion plan..

(b) All Council records, reports, and data must be maintained by the Council for a minimum of 3 years, even if the Council is terminated.

§ 270.14 Update of sector participant data.

The Council will submit to NMFS at the end of each fiscal year an updated list of sector participants who meet the minimum requirements for eligibility to participate in a referendum as stated in the approved charter.

§ 270.15 Quality standards.

(a) Each Council may develop and submit to NMFS for approval or, upon the request of a Council, NMFS will develop quality standards for the species of fish or fish products described in the approved charter. Any quality standard developed under this paragraph must be consistent with the purposes of the Act.

(b) A quality standard developed under paragraph (a) of this section may be adopted by a Council by a majority of its members following a referendum conducted by the Council among sector participants of the concerned sector(s). In order for a quality standard to be brought before Council members for adoption, the majority of the sector participants of the concerned sector(s) must vote in favor of the standard. Further, according to the best available data, the majority must collectively account for, in the 12-month period immediately preceding the month in which the referendum is held, not less than 66 percent of the value of the fish or fish products described in the charter that were handled during such period in that sector by those who meet the eligibility requirements to vote in the referendum as defined by the petitioners.

(c) The Council must submit a plan to conduct the referendum on the quality standards to NMFS for approval at least 60 days in advance of such referendum date. The plan must consist of the following:

(1) Date(s) for conducting the referendum;

(2) Method (by mail or in person);

(3) Copy of the proposed notification to sector participants informing them of the referendum;

(4) List of sector participants eligible to vote;

(5) Name of individuals responsible for conducting the referendum;

(6) Copy of proposed ballot package to be used in the referendum; and

(7) Date(s) and location of ballot counting.

(d) An official observer appointed by NMFS will be allowed to be present at the ballot counting and any other phase of the referendum process, and may take whatever steps NMFS deems appropriate to verify the validity of the process and results of the referendum.

(e) Quality standards developed under this section of the regulations must, at a minimum, meet Food and Drug Administration (FDA) minimum requirements for fish and fish products for human consumption.

(f) Quality standards must be consistent with applicable standards of the U.S. Department of Commerce (National Oceanic and Atmospheric Administration) or other recognized Federal standards and/or specifications for fish and fish products.

(g) No quality standard adopted by a Council may be used in the advertising or promotion of fish or fish products as being inspected by the United States Government unless the standard requires sector participants to be in the U.S. Department of Commerce voluntary seafood inspection program.

(h) The intent of quality standards must not be to discriminate against importers who are not members of the Council.

(i) Quality standards must not be developed for the purpose of creating non-tariff barriers. Such standards must be compatible with U.S. obligations under the General Agreement on Tariffs and Trade, or under other international standards deemed acceptable by NMFS.

(j) The procedures applicable to the adoption and the operation of quality standards developed under this subchapter also apply to subsequent amendments or the termination of such standards.

(k) With respect to a quality standard adopted under this section, the Council must develop and file with NMFS an official identifier in the form of a symbol, stamp, label or seal that will be used to indicate that a fish or fish product meets the quality standard at the time the official identifier is affixed to the fish or fish product, or is affixed to or printed on the packaging material of the fish or fish product. The use of such identifier is governed by § 270.15.

§ 270.16 Deposit of funds.

All funds collected or received by a Council under this section must be deposited in an appropriate account in the name of the Council specified in its charter. Funds eligible to be collected or received by a Council must be limited to those authorized under the Act.

(a) Pending disbursement, under an approved marketing plan and budget, funds collected through assessments authorized by the Act must be deposited in any interest-bearing account or certificate of deposit of a bank that is a member of the Federal Reserve System, or in obligations fully guaranteed as to principal and interest by the United States Government.

(b) The Council may, however, pending disbursement of these funds, invest in risk-free, short-term, interest-bearing instruments.

(1) *Risk-free.* All investments must be insured or fully collateralized with Federal Government securities. In the absence of collateral, accounts established at financial institutions should, in aggregate, total less than $100,000 to assure both principal and interest are federally insured in full.

(2) *Short-term.* Generally, all investments should be for a relatively short time period (one year or less) to assure that the principal is maintained and readily convertible to cash.

(3) *Collateralization.* Investments exceeding the $100,000 insurance coverage level must be fully collateralized by the financial institution.

(i) Collateral must be pledged at face value and must be pledged prior to sending funds to the institution.

(ii) Government securities are acceptable collateral. Declining balance, mortgage backed securities such as Government National Mortgage Association (GNMA) and Federal National Mortgage Association (FNMA) are not acceptable collateral.

(iii) If an account has been established, collateral may be held at the local Federal Reserve Bank. Otherwise, another depository must hold the collateral.

§ 270.17 Authority to impose assessments.

A Council will impose and administer the collection of the assessments that are necessary to pay for all expenses incurred by the Council in carrying out its functions under 50 CFR part 270.

§ 270.18 Method of imposing assessments.

Assessments will be imposed on sector participants in the receiving sector or the importing sector or both as specified in an approved Council charter. Assessment rates will be based on value that may be expressed in monetary units or units of weight or volume.

(a) An assessment on sector participants in the receiving sector will be in the form of a percentage of the value or a fixed amount per unit of weight or volume of the fish described in the charter when purchased by such receivers from fish harvesters.

(b) An assessment on sector participants who own fish processing vessels and harvest the fish described in the charter will be in the form of a percentage of the value or on a fixed amount per unit of weight or volume of the fish described in the charter that is no less than the value if such fish had been purchased by a receiver other than the owner of the harvesting vessel.

(c) An assessment on sector participants in the importing sector will be in the form of a percentage of the value that an importer pays to a foreign supplier, as determined for the purposes of the customs laws, or a fixed amount per unit of weight or volume, of the fish or fish products described in the charter when entered or withdrawn from warehouse for consumption, in the customs territory of the United States by such sector participants.

(d) A Council may not impose an assessment on any person that was not eligible to vote in the referendum establishing the Council by reason of failure to meet the requirements specified under unless that person, after the date on which the referendum is held, meets the requirements of section.

(e) Any person may make voluntary payments or in-kind contributions to a Council for purposes of assisting the Council in carrying out its functions.

§ 270.19 Notice of assessment.

(a) The Council must serve each person subject to assessment with notice that the assessment is due. The notice of assessment must contain:

(1) A specific reference to the provisions of the Act, regulations, charter and referendum that authorize the assessment;

(2) The amount of the assessment;

(3) The period of time covered by the assessment;

(4) The date the assessment is due and payable, which will not be earlier than 30 days from the date of the notice;

(5) The form(s) of payment; and

(6) To whom and where the payment must be made.

(b) The notice must advise such person of his or her right to seek review of the assessment by filing a written petition of objection with NMFS at any time during the time period to which the assessment applies, including the right to request a hearing on the petition. The notice must state that the petition of objection must be filed in accordance with the procedures in § 270.21.

(c) The notice must also advise such persons of his or her right to a refund of the assessment as provided in § 270.22. The notice must state that a refund may be requested for not less than 90 days from such collection, and provide that the Council will make the refund within 60 days after the request for the refund is requested.

§ 270.20 Payment of assessments.

Persons subject to an assessment would be required to pay the assessment on or before the date due, unless they have demanded a refund or filed a petition of objection with NMFS under § 270.21. However, person who have demanded a refund under § 270.22 or filed a petition of objection under § 270.21 may submit proof of these actions in leu of payment. In the case of a petition of objection, NMFs will inform the Council and the petitioner of its finding at which time petitioner must pay the revised assessment if applicable.

§ 270.21 Petition of objection.

(a) *Filing a petition.* Any person issued a notice of assessment under § 270.19 may request that NMFS modify or take other appropriate action regarding the assessment or promotion plan by filing a written petition of objection with NMFS. Petitions of objection may be filed:

(1) Only if the petitioner determines one or more of the following criteria is not in accordance with the law:

(i) The assessment;

(ii) The plan upon which the assessment is based; or

(iii) Any obligation imposed on the petitioner under the plan.

(2) Only during the time period to which the assessment applies.

(b) *Contents of the petition of objection.* A petition must be addressed to Assistant Administrator for Fisheries, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910, and must contain the following:

(1) The petitioner's correct name, address, and principal place of business. If the petitioner is a corporation, this must be stated, together with the date and state of incorporation, and the names, addresses, and respective positions of its officers; if a partnership, the date and place of formation and the name and address of each partner;

(2) The grounds upon which the petition of objection is based, including the specific terms or provisions of the assessment, the marketing and promotion plan, or obligation imposed by the plan, to which the petitioner objects;

(3) A full statement of the facts upon which the petition is based, set forth clearly and concisely, accompanied by any supporting documentation;

(4) The specific relief requested; and

(5) A statement as to whether or not the petitioner requests a hearing.

(c) *Notice to Council.* NMFS will promptly furnish the appropriate Council with a copy of the petition of objection.

(d) *Opportunity for informal hearing.* (1) Any person filing a petition of objection may request an informal hearing on the petition. The hearing request must be submitted with the petition of objection.

(2) If a request for hearing is timely filed, or if NMFS determines that a hearing is advisable, NMFS will so notify the petitioner and the Council. NMFS will establish the applicable procedures, and designate who will be responsible for conducting a hearing. The petitioner, the Council, and any other interested party, may appear at the hearing in person or through a representative, and may submit any relevant materials, data, comments, arguments, or exhibits. NMFS may consolidate two or more hearing requests into a single proceeding.

(3) *Final decision.* Following the hearing, or if no hearing is held, as soon as practicable, NMFS will decide the matter and serve written notice of the decision on the petitioner and the Council. NMFS's decision will be based on a consideration of all relevant documentation and other evidence submitted, and will constitute the final administrative decision and order of the agency. NMFS will have the discretion to waive collection of a contested assessment or revise, modify, or alter the assessment amount based on a Council method of assessment.

§ 270.22 Refunds.

(a) Notwithstanding any other provision of the Act, any person who pays an assessment under the Act may demand and must promptly receive from the Council a refund of such assessment. A demand for refund must be made in accordance with procedures in the approved charter and within such time as will be prescribed by the Council and approved by NMFS. Procedures to provide such a refund must be established before any such assessment may be collected. Such procedures must allow any person to request a refund 90 days or more from such collection, and provide that such refund must be made within 60 days after demand for such refund is made.

(b) Once a refund has been requested by a sector participant and paid by the Council, that sector participant may no longer participate in a referendum or other business of the Council during the remainder of the assessment rate period. Future assessments will only be sent to such a sector participant at the request of the sector participant. If assessments are paid during a future assessment rate period and no refund is requested, that sector participant may again participate in a referendum or other business of the Council.

§ 270.23 Dissolution of Councils.

(a) *Petition for termination.* (1) A petition to terminate a Council may be filed with NMFS by no less than three sector participants in any one sector. Any petition filed under this subsection must be accompanied by a written document explaining the reasons for such petition.

(2) If NMFS determines that a petition filed under paragraph (a)(1) of this section is accompanied by the signatures, or corporate certifications, of no less than three sector participants in the sector referred to in paragraph (a)(1) of this section who collectively accounted for, in the 12-month period immediately preceding the month in which the petition was filed, not less than 20 percent of the value of the fish or fish products described in § 270.3(c)(2)(iii) that were handled by that sector during the period, NMFS within 90 days after the determination, will conduct a referendum for termination of the Council among all sector participants in that sector.

(3) Not less than 30 days prior to holding a referendum, NMFS will publish an announcement in the **Federal Register** of the referendum, including an explanation of the reasons for the petition for termination filed under (a)(1) of this section and any other relevant information NMFS considers appropriate.

(4) If the referendum votes which are cast in favor of terminating the Council constitute a majority of the sector participants voting and the majority, in the period in (a)(2) of this section, collectively accounted for not less than 66 percent of the value of such fish and fish products the that were handled during such period by the sector in paragraph (a)(1) of this section, NMFS will by order terminate the Council effective as of a date by which the affairs of the Council may be concluded on an orderly basis.

(5) NMFS initially will pay all costs of a referendum conducted in section § 270.23. Prior to conducting such a referendum, NMFS will require petitioners to post a bond or other security acceptable to NMFS in an amount which NMFS determines to be sufficient to pay any expenses incurred for the conduct of the referendum.

(6) If a referendum conducted under § 270.23 fails to result in the termination of the Council, NMFS will immediately recover the amount of the bond posted by the petitioners under § 270.23(a)(5).

(7) If a referendum conducted under this subsection results in the termination of the Council, NMFS will recover the expenses incurred for the conduct of the referendum from the account established by the Council. If the amount remaining in such account is insufficient for NMFS to recover all expenses incurred for the conduct of the referendum, NMFS will recover the balance of the expenses from the petitioners that posted a bond under paragraph (a)(5) of this section.

(b) *Payment of remaining funds.* If a Council is terminated under section § 270.23(a)(4), NMFS, after recovering all expenses incurred for the conduct of the referendum under paragraph (a) of this section, will take such action as is necessary and practicable to ensure that moneys remaining in the account established by the Council under § 270.17 are paid on a prorated basis to the sector participants from whom those moneys were collected under § 270.20.

[FR Doc. 06–666 Filed 1–23–06; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register

Vol. 71, No. 15

Tuesday, January 24, 2006

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

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Extension of Public Comment Period on ACHP Formal Comments Regarding the Replacement of a Microwave Communications System in Mount Graham, AZ

AGENCY: Advisory Council on Historic Preservation.

ACTION: Extension of Public Comment Period.

SUMMARY: The Advisory Council on Historic Preservation has extended the public comment period regarding its upcoming issuance formal comments, under the National Historic Presevation Act, to the United States Forest Service regarding its intent to issue a special use permit for the replacement of a microwave communications system in Mount Graham, Arizona.

DATES: Comments must be received on or before February 6, 2006.

ADDRESSES: Address all comments to John L. Nau, III, Chairman, c/o Stephen Del Sordo, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., Suite 809, Washington, DC 20004. Fax (202) 606–8672. Comments may also be submitted by electronic mail to: *sdelsordo@achp.gov.*

FOR FURTHER INFORMATION CONTACT: Stephen Del Sordo, (202) 606–8580. E-mail: *sdelsordo@achp.gov.* Further information may be found in the ACHP Web site: *http://www.achp.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Council on Historic Preservation (ACHP) has extended until February 6, 2006, the public comment period on the replacement of a microwave communications system in Mount Graham (undertaking).

Information on the undertaking was published in the **Federal Register** on January 9, 2006 (71 FR 1406–1407). That notice is available on the ACHP Web site at *http://www.achp.gov.*

The ACHP's membership will use the public input it receives to draft its formal comments to the Forest Service on the undertaking. The ACHP plans to finalize and transmit those comments to the Forest Service on or before February 21, 2006.

Dated: January 18, 2006.

John M. Fowler,

Executive Director.

[FR Doc. 06–602 Filed 1–23–06; 8:45 am]

BILLING CODE 4310–K6–M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket Number FV–05–304]

United States Standards for Grades of Fresh Asparagus

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA) is revising the voluntary United States Standards for Grades of Fresh Asparagus. Specifically, AMS is revising the standards to allow purple and white asparagus to be graded using the standards. This change will bring the standards for asparagus in line with current marketing practices, thereby, improving the usefulness of the standards in serving the industry.

DATES: *Effective Date:* February 23, 2006.

FOR FURTHER INFORMATION CONTACT: Cheri L. Emery, Standardization Section, Fresh Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Ave., SW., Room 1661, South Building, Stop 0240, Washington, DC 20250–0240, (202) 720–2185, fax (202) 720–8871, or e-mail *Cheri.Emery@usda.gov.* The revised United States Standards for Grades of Fresh Asparagus is available either from the above address or by accessing the AMS, Fresh Products Branch Web site at: *http://www.ams.usda.gov/standards/stanfrfv.htm.*

SUPPLEMENTARY INFORMATION: Section 203(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended, directs and authorizes the Secretary of Agriculture ''To develop and improve standards of quality, condition, quantity, grade and packaging and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.'' AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request. The United States Standards for Grades of Fruits and Vegetables not connected with Federal Marketing Orders or U.S. Import Requirements, no longer appear in the Code of Federal Regulations, but are maintained by USDA/AMS/Fruit and Vegetable Programs.

AMS is revising the voluntary United States Standards for Grades of Fresh Asparagus using the procedures that appear in Part 36, Title 7 of the Code of Federal Regulations (7 CFR part 36).

Background

Prior to undertaking detailed work to develop a proposed revision to the standards, AMS published a notice on March 29, 2005 in the **Federal Register** (70 FR 15817) soliciting comments on a possible revision of the United States Standards for Grades of Fresh Asparagus. Based on comments received and information gathered, a second notice was published on October 6, 2005 in the **Federal Register** (70 FR 58370) proposing to revise the standards to allow purple and white asparagus to be graded using the standards. In response to this notice AMS received two comments from Peruvian asparagus organizations supporting the proposed revision. The comments are available by accessing the AMS, Fresh Products Branch Web site at: *http://www.ams.usda.gov/standards/stanfrfv.htm*

The two comments from Peruvian asparagus organizations supporting the proposed revision stated that the revision would facilitate the marketing of fresh asparagus. Based on comments received and information gathered, AMS is revising the fresh asparagus standards to allow purple and white asparagus to be graded using the U.S. standards.

The official grade of a lot of fresh asparagus covered by these standards will be determined by the procedures set forth in the Regulations Governing Inspection, Certification, and Standards

of Fresh Fruits, Vegetables and Other Products (Sec. 51.1 to 51.61).

The United States Standards for Grades of Fresh Asparagus will be effective 30 days after publication of this notice in the **Federal Register**.

Authority: 7 U.S.C. 1621–1627.

Dated: January 18, 2006.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E6–782 Filed 1–23–06; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket Number FV–05–305]

United States Standards for Grades of Globe Artichokes

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA) is revising the United States Standards for Grades of Globe Artichokes. Specifically, AMS is revising the standards to add a U.S. No. 1 Long Stem grade along with an undersize tolerance of 5 percent in the standards. The new grade will have the same requirements as the U.S. No. 1 except that the stems must be smoothly cut to a minimum length of at least 8 inches, unless specified to a longer length in connection with the grade. AMS is further defining ''fairly compact'' by including a definition for ''slightly spread'' to mean, ''the outer scales may be slightly open, but the inner scales at the tip of the artichoke must be closely folded into the bud.'' The revisions would bring the standards for globe artichokes in line with current marketing practices, thereby improving their usefulness in serving the industry.

DATES: *Effective Date:* February 23, 2006.

FOR FURTHER INFORMATION CONTACT: Cheri L. Emery, Standardization Section, Fresh Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 1661 South Building, STOP 0240, Washington, DC 20250–0240, Fax (202) 720–8871 or call (202) 720–2185; E-mail *Cheri.Emery@usda.gov*. The revised United States Standards for Grades of Globe Artichokes will be available either through the address cited above or by accessing the AMS, Fresh Products Branch Web site at: *http://www.ams.usda.gov/standards/stanfrfv.htm*.

SUPPLEMENTARY INFORMATION: Section 203(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended, directs and authorizes the Secretary of Agriculture ''To develop and improve standards of quality, condition, quantity, grade and packaging and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.'' AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request. The United States Standards for Grades of Fruits and Vegetables not connected with Federal Marketing Orders or U.S. Import Requirements, no longer appear in the Code of Federal Regulations, but are maintained by USDA/AMS/Fruit and Vegetable Programs.

AMS is revising the voluntary United States Standards for Grades of Globe Artichokes using procedures that appear in Part 36, Title 7 of the Code of Federal Regulations (7 CFR part 36).

Background

Prior to undertaking work to develop a proposed revision to the standard, AMS published a notice on April 26, 2005, in the **Federal Register** (70 FR 21391) soliciting comments on a possible revision to the United States Standards for Grades of Globe Artichokes. After receiving comments, a second notice was published in the September 12, 2005, **Federal Register** (70 FR 53774) proposing to revise the standards by adding a new grade ''U.S. No. 1 Long Stem'' and further defining ''fairly compact'' by including a definition for ''slightly spread.'' In response to this notice AMS received one comment from an industry group supporting the proposed revision. The comment is available by accessing the AMS, Fresh Products Branch Web site at: *http://www.ams.usda.gov/fv/fpbdocketlist.htm*.

Based on comments received and information gathered, AMS believes the revision to the standards will bring the standards for globe artichokes in line with current marketing practices and thereby improve their usefulness.

The official grade of a lot of globe artichokes covered by these standards is determined by the procedures set forth in the Regulations Governing Inspection, Certification, and Standards of Fresh Fruits, Vegetables and Other Products (Sec. 51.1 to 51.61).

The United States Standards for Grades of Globe Artichokes will become effective 30 days after the publication of this notice in the **Federal Register**.

Authority: 7 U.S.C. 1621–1627.

Dated: January 18, 2006.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E6–785 Filed 1–23–06; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket Number FV–06–301]

United States Standards for Grades of Mixed Commodities

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA) is soliciting comments on the proposed voluntary United States Standards for Grades of Mixed Commodities. This action is being taken at the request of the Fruit and Vegetable Industry Advisory Committee, which asked AMS to identify products that may be better served if grade standards are developed. The proposed standards would provide industry with a common language and uniform basis for trading, thus promoting orderly and efficient marketing of fresh produce shipments containing different commodities packaged in the same container.

DATES: Comments must be received by March 27, 2006.

ADDRESSES: Interested persons are invited to submit written comments to the Standardization Section, Fresh Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Ave., SW., Room 1661, South Building, Stop 0240, Washington, DC 20250–0240, fax (202) 720–8871, e-mail *FPB.DocketClerk@usda.gov*. Comments should make reference to the dates and page number of this issue of the **Federal Register** and will be made available for public inspection in the above office during regular business hours and on the Internet.

The draft of the proposed United States Standards for Grades of Mixed Commodities is available by accessing AMS, Fresh Products Branch Web site at: *http://www.ams.usda.gov/fv/fpbdocketlist.htm*.

FOR FURTHER INFORMATION CONTACT: Cheri L. Emery, at the above address or call (202) 720–2185, e-mail *Cheri.Emery@usda.gov*.

SUPPLEMENTARY INFORMATION: Section 203(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended, directs and authorizes the Secretary of Agriculture to develop and improve standards of quality, condition, quantity, grade and packaging and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices. AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request. The United States Standards for Grades of Fruits and Vegetables not connected with Federal Marketing Orders or U.S. Import Requirements, no longer appear in the Code of Federal Regulations, but are maintained by the USDA/AMS/Fruit and Vegetable Programs.

AMS is proposing to establish voluntary United States Standards for Grades of Mixed Commodities using the procedures that appear in Part 36, Title 7 of the Code of Federal Regulations (7 CFR part 36).

Background

At a meeting of the Fruit and Vegetable Industry Advisory Committee, AMS was asked to identify fresh fruit and vegetables that may be better served if grade standards are developed. AMS identified fresh produce that are uniformly packaged with different types of commodities in the same container, as possibly in need of official grade standards. Such standards are used by the fresh produce industry to describe the products they are trading, thus facilitating the marketing of those products.

AMS has developed proposed voluntary grade standards for shipments of mixed commodities. These standards would establish a grade U.S. Mixed as well as sections pertaining to sampling, tolerances, application of tolerances, and definitions for Injury, Damage and Serious Damage.

The adoption of these proposed standards would provide the ever expanding mixed commodity industry with U.S. grade standards similar to those extensively in use by the fresh produce industry to assist in orderly marketing of other commodities.

The official grade of a lot of mixed commodities covered by these standards will be determined by the procedures set forth in the Regulations Governing Inspection, Certification, and Standards of Fresh Fruits, Vegetables and Other Products (Sec. 51.1 to 51.61).

This notice provides for a 60 day comment period for interested parties to comment on the proposed United States Standards for Grades of Mixed Commodities.

Authority: 7 U.S.C. 1621–1627.

Dated: January 18, 2006.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E6–780 Filed 1–23–06; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket Number FV–05–308]

United States Standards for Grades of Pea Pods

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA) is soliciting comments on the proposed voluntary United States Standards for Grades of Pea Pods. This action is being taken at the request of the Fruit and Vegetable Industry Advisory Committee, which asked AMS to identify commodities that may be better served if grade standards are developed. The proposed standards would provide industry with a common language and uniform basis for trading, thus promoting the orderly and efficient marketing of pea pods.

DATES: Comments must be received by March 27, 2006.

ADDRESSES: Interested persons are invited to submit written comments to the Standardization Section, Fresh Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Ave., SW., Room 1661 South Building, Stop 0240, Washington, DC 20250–0240; Fax (202) 720–8871, E-mail *FPB.DocketClerk@usda.gov*. Comments should make reference to the dates and page number of this issue of the **Federal Register** and will be made available for public inspection in the above office during regular business hours and on the Internet.

The draft of the proposed United States Standards for Grades of Pea Pods is available by accessing AMS, Fresh Products Branch Web site at: *http://www.ams.usda.gov/fv/fpbdocketlist.htm*.

FOR FURTHER INFORMATION CONTACT: Cheri L. Emery, at the above address or call (202) 720–2185; E-mail *Cheri.Emery@usda.gov*.

SUPPLEMENTARY INFORMATION: Section 203(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended, directs and authorizes the Secretary of Agriculture ''To develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.'' AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request. The United States Standards for Grades of Fruits and Vegetables that are not requirements of Federal Marketing Orders or U.S. Import Requirements, no longer appear in the Code of Federal Regulations, but are maintained by USDA, AMS, Fruit and Vegetable Programs.

AMS is proposing to establish voluntary United States Standards for Grades of Pea Pods using the procedures that appear in Part 36, Title 7 of the Code of Federal Regulations (7 CFR part 36).

Background

At a meeting of the Fruit and Vegetable Industry Advisory Committee, AMS was asked to identify fresh fruit and vegetables that may be better served if grade standards are developed. As a result, AMS identified pea pods, or as they are sometimes called snow peas, as a commodity possibly in need of official grade standards. Such standards are used by the fresh produce industry to describe the product they are trading, thus facilitating the marketing of the product.

Prior to undertaking research and other work associated to develop the standards, AMS published a notice on May 2, 2005 in the **Federal Register** (70 FR 83) soliciting comments on the possible development of the United States Standards for Grades of Pea Pods.

In response to the request for comments, AMS received one comment on the development of U.S. standards for pea pods. The comment was from an industry group that expressed support for the development of standards for pea pods. The comment is available by accessing AMS, Fresh Products Branch Web site at: *http://www.ams.usda.gov/fvfpbdocketlist.htm*. Based on the

comment received and information gathered, AMS has developed proposed grade standards for pea pods. This proposal would establish the following grades, as well as a tolerance for each grade: U.S. Fancy and U.S. No. 1. In addition, there are proposed ''Tolerances,'' and ''Application of Tolerances'' sections. AMS is proposing to define ''Injury,'' ''Damage'' and ''Serious Damage,'' along with specific basic requirements and definitions for defects.

The official grade of a lot or shipment of fresh vegetables covered by U.S. standards is determined by the procedures set forth in the Regulations Governing Inspection, Certification, and Standards of Fresh Fruits, Vegetables and Other Products (Sec. 51.1 to 51.61).

This notice provides for a 60-day comment period for interested parties to comment on the proposed United States Standards for Grades of Pea Pods.

Authority: 7 U.S.C. 1621–1627.

Dated: January 18, 2006.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E6–784 Filed 1–23–06; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket Number FV–05–301]

United States Standards for Grades of Strawberries

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA) is revising the United States Standards for Grades of Strawberries. AMS received a request from an industry group to modify the standards to allow that percentages be determined by count and not volume. The change will make tolerance determination more objective and more uniform.

DATES: Effective Date: February 23, 2006.

FOR FURTHER INFORMATION CONTACT: Cheri L. Emery, Standardization Section, Fresh Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 1661 South Building, STOP 0240, Washington, DC 20250–0240, Fax (202) 720–8871 or call (202) 720–2185; E-mail *Cheri.Emery@usda.gov*. The revised United States Standards for Grades of Strawberries will be available either through the address cited above or by accessing the AMS, Fresh Products Branch Web site at: *http://www.ams.usda.gov/standards/stanfrfv.htm*.

SUPPLEMENTARY INFORMATION: Section 203(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended, directs and authorizes the Secretary of Agriculture ''To develop and improve standards of quality, condition, quantity, grade and packaging and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.'' AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request. The United States Standards for Grades of Fruits and Vegetables not connected with Federal Marketing Orders or U.S. Import Requirements, no longer appear in the Code of Federal Regulations, but are maintained by USDA/AMS/Fruit and Vegetable Programs.

AMS is revising the voluntary United States Standards for Grades of Strawberries using procedures that appear in Part 36, Title 7 of the Code of Federal Regulations (7 CFR part 36).

Background

Prior to undertaking detailed work to develop a proposed revision to the standard, AMS published a notice on March 11, 2005, in the **Federal Register** (70 FR 12175) soliciting comments on a possible revision to the United States Standards for Grades of Strawberries. After receiving comments, a second notice was published in the September 7, 2005, **Federal Register** (70 FR 53148–9) concerning the proposed percentage determination. In response to this notice, AMS received one comment from a state agricultural representative opposing the proposed revision. The comment is available by accessing the AMS, Fresh Products Branch Web site at: *http://www.ams.usda.gov/fv/fpbdocketlist.htm*.

The comment stated that the size variance is too great to make a count-based inspection an accurate representation of the lot and that maybe the commodity should be inspected by weight. However, AMS believes that allowing percentages to be determined by count and not volume would establish a uniform procedure for determining the percentages, thereby providing more objectivity to an inspection.

Additionally, AMS is eliminating the unclassified category. This section is being removed in all standards, when they are revised. This category is not a grade and only serves to show that no grade has been applied to the lot. It is no longer considered necessary.

The official grade of a lot of strawberries covered by these standards is determined by the procedures set forth in the Regulations Governing Inspection, Certification, and Standards of Fresh Fruits, Vegetables and Other Products (Sec. 51.1 to 51.61).

The United States Standards for Grades of Strawberries will become effective 30 days after the publication of this notice in the **Federal Register**.

Authority: 7 U.S.C. 1621–1627.

Dated: January 18, 2006.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E6–781 Filed 1–23–06; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket Number FV–06–304]

United States Standards for Grades of Table Grapes (European or Vinifera Type)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA), is soliciting comments on a proposal to revise the United States Standards for Grades of Table Grapes (European or Vinifera Type). AMS has received petitions from the California Grape and Tree Fruit League and Western Growers Association, requesting that the current standards be modified by adding a 10 percent allowance for shattered berries in consumer containers for en route or at destination.

DATES: Comments must be received by March 27, 2006.

ADDRESSES: Interested persons are invited to submit written comments to the Standardization Section, Fresh Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Ave., SW., Room 1661 South Building, Stop 0240, Washington, DC 20250–0240; Fax (202) 720–8871, E-mail

FPB.DocketClerk@usda.gov. Comments should make reference to the dates and page number of this issue of the **Federal Register** and will be made available for public inspection in the above office during regular business hours. The United States Standards for Grades of Table Grapes (European or Vinifera Type) are available either through the address cited above or by accessing the AMS, Fresh Products Branch Web site at: *http://www.ams.usda.gov/standards/stanfrfv.htm.*

FOR FURTHER INFORMATION CONTACT: Cheri L. Emery, at the above address or call (202) 720–2185, E-mail *Cheri.Emery@usda.gov.*

SUPPLEMENTARY INFORMATION: Section 203(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended, directs and authorizes the Secretary of Agriculture ''To develop and improve standards of quality, condition, quantity, grade and packaging and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.'' AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural commodities and makes copies of official standards available upon request.

Background

AMS received petitions from the California Grape and Tree Fruit League and Western Growers Association, requesting a revision to the United States Standards for Grades of Table Grapes (European or Vinifera Type). These standards were last revised in 1999. The petitioners represent more than 85 percent of the European or Vinifera type table grape production in the United States.

The petitioners are requesting that AMS revise the standards to provide a 10 percent allowance for shattered berries in consumer containers for en route or at destination. Shattered means that the berry is detached from the bunch. The standards currently provide a 12 percent total tolerance for bunches and berries failing to meet the requirements of grade for en route or at destination. Revising the standards to include a separate 10 percent allowance would mean that shattered berries would not be scored as a defect against the 12 percent total tolerance until the amount of shattered berries exceeds the 10 percent allowance. For example: (1) A lot of berries which has 22 percent shattered berries 12 percent would be reported as a defect, this lot would meet the requirements of the U.S. No. 1 Table grade provided no other defects were present; (2) a lot of berries which has 23 percent shattered berries 13 percent would be reported as a defect which would cause the lot to fail meet the requirements of the U.S. No. Table 1 grade by 1 percent. The petitioners stated that they feel change, specific to consumer containers, is warranted as the majority of table grapes are now being sold in consumer containers which allows shattered berries to be fully utilized/sold. This does not hold true for shattered berries in bulk containers, as these berries remain loose in the container, therefore, limiting the ability to fully utilize/sell the shattered berries.

Prior to undertaking detailed work to develop a proposed revision to the standards, AMS is soliciting comments on the petition submitted to revise the United States Standards for Grades of Table Grapes (European or Vinifera Type).

This notice provides for a 60-day comment period for interested parties to comment on changes to the standards. Should AMS conclude that revisions are needed, the Agency will develop a proposed revised standard that will be published in the **Federal Register** with a request for comments.

Authority: 7 U.S.C. 1621–1627.

Dated: January 18, 2006.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E6–783 Filed 1–23–06; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Summer Food Service Program for Children Program Reimbursement for 2006

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice informs the public of the annual adjustments to the reimbursement rates for meals served in the Summer Food Service Program for Children (SFSP). These adjustments reflect changes in the Consumer Price Index and are required by the statute governing the Program. In addition, further adjustments are made to these rates to reflect the higher costs of providing meals in the States of Alaska and Hawaii, as authorized by the William F. Goodling Child Nutrition Reauthorization Act of 1998.

DATES: *Effective Date:* January 1, 2006.

FOR FURTHER INFORMATION CONTACT: Robert M. Eadie, Branch Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302, (703) 305–2590.

SUPPLEMENTARY INFORMATION: This program is listed in the Catalog of Federal Domestic Assistance under No. 10.559 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials (7 CFR part 3015, subpart V, and final rule related notice published at 48 FR 29114, June 24, 1983).

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3518), no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

This notice is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act. Additionally, this notice has been determined to be exempt from review by the Office of Management and Budget under Executive Order 12866.

Definitions

The terms used in this Notice shall have the meaning ascribed to them in the regulations governing the Summer Food Service Program for Children (7 CFR part 225).

Background

In accordance with Section 13 of the National School Lunch Act (NSLA) (42 U.S.C. 1761) and the regulations governing the SFSP (7 CFR part 225), notice is hereby given of adjustments in Program payments for meals served to children participating in the SFSP in 2006. Adjustments are based on changes in the food away from home series of the Consumer Price Index (CPI) for All Urban Consumers for the period November 2004 through November 2005.

Section 104(a) of the William F. Goodling Child Nutrition Reauthorization Act of 1998 (Public Law 105–336) amended Section 12(f) of the NSLA (42 U.S.C. 1760(f)) to allow adjustments to SFSP reimbursement rates to reflect the higher cost of providing meals in the SFSP in Alaska and Hawaii. Therefore, this notice contains adjusted rates for Alaska and Hawaii. This change was made in an effort to be consistent with other Child Nutrition Programs, such as the National School Lunch Program and the

School Breakfast Program, which already had the authority to provide higher reimbursement rates for programs in Alaska and Hawaii.

The 2006 reimbursement rates, in dollars, for all States excluding Alaska and Hawaii:

MAXIMUM PER MEAL REIMBURSEMENT RATES FOR ALL STATES (NOT AK OR HI)

	Operating costs	Administrative costs	
		Rural or self-preparation sites	Other types of sites
Breakfast	$1.47	$.1450	$.1150
Lunch or Supper	2.56	.2675	.2225
Supplement	.59	.0725	.0575

The 2006 reimbursement rates, in dollars, for Alaska:

MAXIMUM PER MEAL REIMBURSEMENT RATES FOR ALASKA ONLY

	Operating costs	Administrative costs	
		Rural or self-preparation sites	Other types of sites
Breakfast	$2.38	$.2350	$.1875
Lunch or Supper	4.15	.4350	.3600
Supplement	.97	.1175	.0925

The 2006 reimbursement rates, in dollars, for Hawaii:

MAXIMUM PER MEAL REIMBURSEMENT RATES FOR HAWAII ONLY

	Operating costs	Administrative costs	
		Rural or self-preparation sites	Other types of sites
Breakfast	$1.72	$.1700	$.1350
Lunch or Supper	3.00	.3125	.2600
Supplement	.70	.0850	.0675

The total amount of payments to State agencies for disbursement to Program sponsors will be based upon these Program reimbursement rates and the number of meals of each type served. The above reimbursement rates, for both operating and administrative reimbursement rates, represent a 3.2 percent increase during 2005 (from 189.6 in November 2004 to 195.6 in November 2005) in the food away from home series of the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics of the Department of Labor. The Department would like to point out that the SFSP administrative reimbursement rates continue to be adjusted up or down to the nearest quarter-cent, as has previously been the case. Additionally, operating reimbursement rates have been rounded down to the nearest whole cent, as required by Section 11(a)(3)(B) of the NSLA (42 U.S.C. 1759 (a)(3)(B)).

Authority: Secs. 9, 13 and 14, National School Lunch Act, as amended (42 U.S.C. 1758, 1761, and 1762a).

Dated: January 17, 2006.

Roberto Salazar,

Administrator.

[FR Doc. E6–793 Filed 1–23–06; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Southwest Mississippi Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Meeting notice for the Southwest Mississippi Resource Advisory Committee under Section 205 of the Secure Rural Schools and Community Self Determination Act of 2000 (Public Law 106–393

SUMMARY: This notice is published in accordance with section 10(a)(2) of the Federal Advisory Committee Act. Meeting notice is hereby given for the southwest Mississippi Resource Advisory Committee pursuant to Section 205 of the Secure Rural Schools and Community Self Determination Act of 2000, Public Law 106–393. Topics to be discussed include: General information, possible Title II projects, and next meeting dates and agendas.

DATES: The meeting will be held on February 28, 2006, from 6 p.m. and end at approximately 9 p.m.

ADDRESSES: The meeting will be held at the Franklin County Public Library, 381 First Street, Meadville, Mississippi.

FOR FURTHER INFORMATION CONTACT: Mary Bell Lunsford, Public Affairs Officer, USDA, Homochitto National Forest, 1200 Hwy. 184 East, Meadville, MS 39653 (601–384–5876).

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Committee discussion is limited to Forest Service staff, Committee members and elected officials. However, persons who wish to bring matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting. A public input session will be provided and individuals who made written requests by February 21, 2006, will have the opportunity to address the committee at that session. Individuals wishing to speak or propose agenda items must send their names and proposals to Tim Reed, District Ranger, DFO, 1200 Hwy. 184 East, Meadville, MS 39653.

Dated: January 13, 2006.

Tim Reed,

Designated Federal Officer.

[FR Doc. 06–606 Filed 1–23–06; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Lincoln County Resource Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Public Law 92–463) and under the Secure Rural Schools and Community Self-Determination Act of 2000 (Public Law 106–393) the Kootenai National Forest's Lincoln County Resource Advisory Committee will meet on Wednesday February 1, 2006 at 6 p.m. at the Forest Supervisor's Office in Libby, Montana for a business meeting. The meeting is open to the public.

DATES: February 1, 2006.

ADDRESSES: Forest Supervisor's Office, 1101 U.S. Hwy. 2 West, Libby, Montana.

FOR FURTHER INFORMATION CONTACT: Barbara Edgmon, Committee Coordinator, Kootenai National Forest at (406) 283–7764, or e-mail *bedgmon@fs.fed.us.*

SUPPLEMENTARY INFORMATION: Agenda topics include status of approved projects, plan for receiving and approving proposals for 2007, and receiving public comment. If the meeting date or location is changed, notice will be posted in the local newspapers, including the daily Interlake based in Kalispell, Montana.

Dated: January 17, 2006.

Bob Castaneda,

Forest Supervisor.

[FR Doc. 06–615 Filed 1–23–06; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Notice of Solicitation for Sea Grant Review Panelists

AGENCY: National Oceanic and Atmospheric Administration Office of Oceanic and Atmospheric Research (OAR) National Sea Grant Review Panel.

SUMMARY: This notice responds to the National Sea Grant College Program Act, at 33 U.S.C. 1128, which requires the Secretary of Commerce to solicit nominations at least once a year for membership on the Sea Grant Review Panel. This advisory committee provides advice on the implementation of the National Sea Grant College Program.

DATES: Resumes should be sent to the address specified and must be received by 30 days from publication.

ADDRESSES: Dr. Leon M. Cammen, Interim Executive Director; National Sea Grant College Program; 1315 East-West Highway, Room 11841; Silver Spring, Maryland 20910

FOR FURTHER INFORMATION CONTACT: Dr. Leon M. Cammen of the National Sea Grant College Program at the address given above; telephone (301) 713–2435 extension 136 or fax number (301) 713–0799.

SUPPLEMENTARY INFORMATION: Section 209 of the Act establishes a Sea Grant Review Panel to advise the Secretary of Commerce, the Under Secretary for Oceans and Atmosphere, and the Director of the National Sea Grant College Program on the implementation of the Sea Grant Program. The panel provides advice on such matters as:

(a) The Sea Grant Fellowship Program;

(b) Applications or proposals for, and performance under, grants and contracts awarded under the Sea Grant Program Improvement Act of 1976, as amended at 33 U.S.C. 1124;

(c) The designation and operation of sea grant colleges and sea grant institutes; and the operation of the sea grant program;

(d) The formulation and application of the planning guidelines and priorities under 33 U.S.C. 1123 (a) and (c)(1); and

(e) Such other matters as the Secretary refers to the panel for review and advice.

The Panel is to consist of 15 voting members composed as follows: Not less than eight of the voting members of the panel should be individuals who, by reason of knowledge, experience, or training, are especially qualified in one or more of the disciplines and fields included in marine science. The other voting members shall be individuals who by reason of knowledge, experience, or training, are especially qualified in, or representative of, education, extension service, state government, industry, economics, planning, or any other activity which is appropriate to, and important for, any effort to enhance the understanding, assessment, development, utilization, or conservation of ocean and coastal resources. No individual is eligible to be a voting member of the panel if the individual is (a) the director of a sea grant college, sea grant regional consortium, or sea grant program, (b) an applicant for or beneficiary (as determined by the Secretary) of any grant or contract under 33 U.S.C. 1124 or (c) a full-time officer or employee of the United States. The Director of the National Sea Grant College Program and one Director of a Sea Grant Program also serve as non-voting members. Panel members are appointed for a 4-year term.

Dated: January 18, 2006.

Mark E. Brown,

Chief Financial Officer, Office of Oceanic and Atmospheric Research.

[FR Doc. E6–830 Filed 1–23–06; 8:45 am]

BILLING CODE 3510–KA–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Transportation and Related Equipment Technical Advisory Committee; Notice of Open Meeting

The Transportation and Related Equipment Technical Advisory Committee will meet on February 9, 2006, 9:30 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Pennsylvania and Constitution Avenues, NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to transportation and related equipment or technology.

Agenda

1. Welcome and Introductions.
2. Review of Bureau issues of significance to TRANSTAC members.

3. Regulatory overview.
4. Policy overview.
5. Missile Technology Control Regime.
6. Wassenaar proposal status.
7. Jurisdiction technical working group report.
8. Presentation of papers and comments by the public.
9. Follow-up on open action items.

The meeting will be open to the public and a limited number of seats will be available. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that presenters forward the public presentation materials to Yvette Springer at *Yspringer@bis.doc.gov*. For more information contact Ms. Springer on (202) 482–4814.

Dated: January 17, 2006.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 06–589 Filed 1–23–06; 8:45 am]

BILLING CODE 3510–JT–M

DEPARTMENT OF COMMERCE

International Trade Administration

(A–122–840)

Notice of Final Results of Antidumping Duty Administrative Review: Carbon and Certain Alloy Steel Wire Rod from Canada

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On July 20, 2005, the Department of Commerce (the Department) published the preliminary results of its second administrative review of the antidumping duty order on carbon and certain alloy steel wire rod from Canada. The review covers two producers of the subject merchandise, Ivaco Inc. and Ivaco Rolling Mills (IRM) (collectively, ''Ivaco'') and Ispat Sidbec, Inc. (Ispat) (now known as Mittal Canada Inc. (Mittal)[1]). The period of review (POR) is October 1, 2003, through September 30, 2004. Based on our analysis of comments received, these final results differ from the preliminary results. The final results are listed below in the Final Results of Review section.

EFFECTIVE DATE: January 24, 2006.

FOR FURTHER INFORMATION CONTACT: Salim Bhabhrawala or David Neubacher, at (202) 482–1784 or (202) 482–5823, respectively; AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On July 20, 2005, the Department published in the **Federal Register** the preliminary results of the second administrative review of the antidumping duty order on carbon and certain alloy steel wire rod from Canada. *See Notice of Preliminary Results of Antidumping Duty Administrative Review: Carbon and Certain Steel Alloy Steel Wire Rod from Canada*, 70 FR 41681 (July 20, 2005) (*Preliminary Results*).

We invited parties to comment on the *Preliminary Results*. On August 29, 2005, we received case briefs from the respondents, Ivaco and Ispat, and the petitioners, Gerdau Ameristeel US Inc., ISG Georgetown Inc., Keystone Consolidated Industries, Inc., and North Star Steel Texas, Inc. All parties submitted rebuttal briefs on September 9, 2005. No public hearing was requested.

Scope of the Order

The merchandise subject to this order is certain hot–rolled products of carbon steel and alloy steel, in coils, of approximately round cross section, 5.00 mm or more, but less than 19.00 mm, in solid cross-sectional diameter.

Specifically excluded are steel products possessing the above–noted physical characteristics and meeting the Harmonized Tariff Schedule of the United States (HTSUS) definitions for (a) stainless steel; (b) tool steel; c) high nickel steel; (d) ball bearing steel; and (e) concrete reinforcing bars and rods. Also excluded are (f) free machining steel products (*i.e.*, products that contain by weight one or more of the following elements: 0.03 percent or more of lead, 0.05 percent or more of bismuth, 0.08 percent or more of sulfur, more than 0.04 percent of phosphorus, more than 0.05 percent of selenium, or more than 0.01 percent of tellurium).

Also excluded from the scope are 1080 grade tire cord quality wire rod and 1080 grade tire bead quality wire rod. Grade 1080 tire cord quality rod is defined as: (i) grade 1080 tire cord quality wire rod measuring 5.0 mm or more but not more than 6.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no non–deformable inclusions greater than 20 microns and no deformable inclusions greater than 35 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.15 mm; (vi) capable of being drawn to a diameter of 0.30 mm or less with 3 or fewer breaks per ton, and (vii) containing by weight the following elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.006 percent or less of nitrogen, and (5) not more than 0.15 percent, in the aggregate, of copper, nickel and chromium.

Grade 1080 tire bead quality rod is defined as: (i) grade 1080 tire bead quality wire rod measuring 5.5 mm or more but not more than 7.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no non–deformable inclusions greater than 20 microns and no deformable inclusions greater than 35 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.2 mm; (vi) capable of being drawn to a diameter of 0.78 mm or larger with 0.5 or fewer breaks per ton; and (vii) containing by weight the following elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of soluble aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.008 percent or less of nitrogen, and (5) either not more than 0.15 percent, in the aggregate, of copper, nickel and chromium (if chromium is not specified), or not more than 0.10 percent in the aggregate of copper and nickel and a chromium content of 0.24 to 0.30 percent (if chromium is specified).

For purposes of grade 1080 tire cord quality wire rod and grade 1080 tire bead quality wire rod, an inclusion will be considered to be deformable if its ratio of length (measured along the axis – that is, the direction of rolling – of the rod) over thickness (measured on the same inclusion in a direction perpendicular to the axis of the rod) is

[1] On June 24, 2005, we determined that Mittal was the successor-in-interest to Ispat Sidbec, Inc. *See Final Results of Changed Circumstances Antidumping Duty Administrative Review: Carbon and Certain Steel Alloy Wire Rod from Canada*, 70 FR 39484 (July 8, 2005).

equal to or greater than three. The size of an inclusion for purposes of the 20 microns and 35 microns limitations is the measurement of the largest dimension observed on a longitudinal section measured in a direction perpendicular to the axis of the rod. This measurement methodology applies only to inclusions on certain grade 1080 tire cord quality wire rod and certain grade 1080 tire bead quality wire rod that are entered, or withdrawn from warehouse, for consumption on or after July 24, 2003.

The designation of the products as ''tire cord quality'' or ''tire bead quality'' indicates the acceptability of the product for use in the production of tire cord, tire bead, or wire for use in other rubber reinforcement applications such as hose wire. These quality designations are presumed to indicate that these products are being used in tire cord, tire bead, and other rubber reinforcement applications, and such merchandise intended for the tire cord, tire bead, or other rubber reinforcement applications is not included in the scope. However, should petitioners or other interested parties provide a reasonable basis to believe or suspect that there exists a pattern of importation of such products for other than those applications, end–use certification for the importation of such products may be required. Under such circumstances, only the importers of record would normally be required to certify the end use of the imported merchandise.

All products meeting the physical description of subject merchandise that are not specifically excluded are included in this scope.

The products under review are currently classifiable under subheadings 7213.91.3010, 7213.91.3015, 7213.91.3090, 7213.91.3092, 7213.91.4510, 7213.91.4590, 7213.91.6010, 7213.91.6090, 7213.99.0031, 7213.99.0038, 7213.99.0090, 7227.20.0010, 7227.20.0020, 7227.20.0090, 7227.20.0095, 7227.90.6010, 7227.90.6051, 7227.90.6053, 7227.90.6058, 7227.90.6059, and 7227.90.6080 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.

Analysis of Comments Received

The issues raised in the case briefs by parties to this administrative review are addressed in the *Issues and Decision Memorandum* to David M. Spooner, Assistant Secretary for Import Administration, from Stephen J. Claeys, Deputy Assistant Secretary (*Decision Memorandum*), which is hereby adopted by this notice. A list of the issues addressed in the *Decision Memorandum* is appended to this notice. The *Decision Memorandum* is on file in the Central Records Unit in Room B–099 of the main Commerce building, and can also be accessed directly on the Web at *http://ia.ita.doc.gov/frn/index.html*. The paper copy and electronic version of the *Decision Memorandum* are identical in content.

Changes Since the Preliminary Results

Based on our analysis of comments received, we have made adjustments to the preliminary results calculation methodologies in calculating the final dumping margins. Brief descriptions of the company–specific changes are provided below and the changes are discussed in detail in the *Decision Memorandum*.

Ivaco

We have corrected ministerial errors identified by parties in Ivaco's preliminary margin calculations as follows: (1) we included indirect selling expenses in the calculation of CEP profit; (2) we used Ivaco's reported credit expenses for its U.S. currency denominated sales in the home market and assigned it correctly throughout the calculation program; (3) we readjusted Ivaco's date of sale on certain U.S. sales; and (4) we ensured that the freight expenses from the border to the further processors were counted as a further manufacturing expense for only those sales which underwent further manufacturing in the United States.

Ispat

We have corrected ministerial errors identified by parties in Ispat's preliminary margin calculations as follows: (1) we included the correct database and allowed for an offset in the calculation of CEP profit within the margin program; and (2) we have corrected the calculation of the CEP offset in the margin program.

Final Results of Review

As a result of our review, we determine that the following weighted–average margins exist for the period of October 1, 2003, through September 30, 2004:

Producer	Weighted–Average Margin (Percentage)
Ivaco	3.08
Ispat/Mittal	6.13

Assessment

The Department will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries, pursuant to 19 CFR 351.212(b). The Department calculated importer–specific duty assessment rates on the basis of the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the examined sales for that importer. Where the assessment rate is above *de minimis*, we will instruct CBP to assess duties on all entries of subject merchandise by that importer. In accordance with 19 CFR 356.8(a), the Department will issue appropriate assessment instructions directly to CBP on or after 41 days following the date of publication of these final results of review.

Cash Deposits

Furthermore, the following deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of carbon and certain alloy steel wire rod from Canada entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results, as provided by section 751(a) of the Tariff Act of 1930, as amended (the Act): (1) for companies covered by this review, the cash deposit rate will be the rate listed above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company–specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the investigation, but the producer is, the cash deposit rate will be that established for the producer of the merchandise in these final results of review, a prior review, or in the final determination; and (4) if neither the exporter nor the producer is a firm covered in this review, a prior review, or the investigation, the cash deposit rate will be 8.11 percent, the ''All Others'' rate established in the less–than-fair–value investigation. These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402 (f) 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 in the subsequent assessment of double antidumping duties.

This notice also is the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. 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 the terms of an APO is a sanctionable violation.

We are issuing and publishing these results and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 17, 2006.

David M. Spooner,

Assistant Secretaryfor Import Administration.

APPENDIX

I. General Issues

Comment 1: Freight to Unaffiliated Processors as Further Manufacturing

II. Company Specific Issues

Issues Specific to Ivaco

Comment 2: Use of Level of Trade Adjustment for IRM's and Sivaco's U.S. Sales

Comment 3: Level of Trade Methodology Used for IRM's and Sivaco's U.S. Sales

Comment 4: Ministerial Error Allegations Specific to Ivaco

Issues Specific to Ispat

Comment 5: Cost Averaging Periods

Comment 6: CEP Profit

Comment 7: Negative Net–Prices for U.S. Sales

Comment 8: Treatment of Certain Sales as CEP Sales

Comment 9: Offsetting for Export Sales that Exceed Normal Value

Comment 10: Ministerial Error Allegations Specific to Ispat

[FR Doc. E6–823 Filed 1–23–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

(A–821–802)

Extension of Time Limit for Sunset Review of the Agreement Suspending the Antidumping Investigation on Uranium from the Russian Federation

AGENCY: Import Administration, International Trade Administration, U.S. Department of Commerce.

EFFECTIVE DATE: January 24, 2006.

FOR FURTHER INFORMATION CONTACT: Sally C. Gannon or Aishe Allen, Import Administration, International Trade Administration, U.S. Department of Commerce. 14th Street and Constitution Avenue, NW., Washington, DC 20230; (202) 482–0162 or (202) 482–0172, respectively.

Extension of Time Limit for Sunset Review:

On November 10, 2005, the Department of Commerce (''the Department'') extended the time limit for the sunset review of the agreement suspending the antidumping investigation on uranium from the Russian Federation in accordance with section 751(c)(5)(B) of the Tariff Act of 1930, as amended (''the Act''). *See Extension of Time Limit for Sunset Review of the Agreement Suspending the Antidumping Investigation on Uranium from the Russian Federation*, 70 FR 68397 (November 10, 2005) (''*Notice of Extension*''). The Department has now determined to conduct a full sunset review of this suspended investigation. See Memorandum from Sally C. Gannon to Ronald K. Lorentzen; ''Sunset Review of Uranium from the Russian Federation: Adequacy of Domestic and Respondent Interested Party Responses to the Notice of Initiation and Decision to Conduct Full Sunset Review,'' dated January 17, 2006.

Pursuant to section 351.218(f) of the Department's regulations, the Department normally will issue its preliminary results in a full sunset review not later that 110 days after the date of publication in the **Federal Register** of the notice of initiation. However, as determined in *Notice of Extension*, the sunset review of the agreement suspending the antidumping investigation on uranium from the Russian Federation is extraordinarily complicated and requires additional time for the Department to complete its analysis. Therefore, the Department is extending the deadline for the preliminary results in this proceeding by additional 30 days and, as a result, intends to issue the preliminary results of the full sunset review no later than February 17, 2006. The Department will issue its final results of the full sunset review on May 30, 2006, as specified in the *Notice of Extension*.

This notice is issued in accordance with sections 751(c)(5)(B) and (C)(v) of the Act.

Dated: January 17, 2006.

Ronald K. Lorentzen,

DirectorOffice of Policy.

[FR Doc. E6–825 Filed 1–23–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–501]

Notice of Amended Final Results of Antidumping Duty Administrative Review: Certain Welded Carbon Steel Pipe and Tube from Turkey

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 5, 2005, the Department of Commerce (''the Department'') issued the final results of its administrative review of the antidumping duty order on certain welded carbon steel pipe and tube (''welded pipe and tube'') from Turkey.[1] The period of review is May 1, 2003, through April 30, 2004. Based on the correction of certain ministerial errors, we have changed the margins for the Borusan Group (''Borusan'') and for the Yucel Group, which includes Cayirova Boru Sanayi ve Ticaret A.S. and its affiliate, Yucel Boru Ithalat–Ihracat ve Pazarlama A.S. (collectively referred to as ''Cayirova'').

EFFECTIVE DATE: January 24, 2006.

FOR FURTHER INFORMATION CONTACT: Christopher Hargett, George McMahon, or Jim Terpstra, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–4161, (202) 482–1167 or (202) 482–3965, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 12, 2005, the Department published in the **Federal Register** the final results of the

[1] *See Notice of Final Results of Antidumping Duty Administrative Review: Certain Welded Carbon Steel Pipe and Tube from Turkey*, 70 FR 73447 (December 12, 2005).

administrative review of the antidumping duty order on welded pipe and tube from Turkey. We received timely allegations of ministerial errors from Borusan and Cayirova. In its comments dated December 9, 2005, Borusan alleged that the Department erred in that it did not include certain U.S. sales in the margin program. In its comments dated December 12, 2005, Cayirova alleged that the Department erred in the revised credit calculation in the home market (CREDITH). Petitioner did not comment on the ministerial errors alleged by respondents.[2] We agree with respondents that these errors are ministerial errors and have amended the final results to correct the errors referenced herein. For a full explanation of changes made by the Department, please see the Memorandum from Melissa G. Skinner to Stephen J. Claeys, Deputy Assistant Secretary for Import Administration, *Ministerial Error Allegations Concerning the Notice of Final Results of Antidumping Duty Administrative Review on Certain Welded Carbon Steel Pipe and Tube from Turkey*, available in the Central Records Unit, room B099 of the main Department building.

Amended Final Results of Review

As a result of the correction of ministerial errors, the following weighted–average percentage margins exist for the period May 1, 2003, through April 30, 2004:

Manufacturer/Exporter	Margin (percent)	Amended Margin (percent)
Borusan	0.86	0.74
Cayirova	3.52	3.28

The Department shall determine, and the U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries. In accordance with section 351.212(b)(1) of the Department's regulations, we have calculated importer–specific assessment rates by dividing the dumping margin found on the subject merchandise examined by the entered value of such merchandise. Where the importer–specific assessment rate is above *de minimis*, we will instruct CBP to assess antidumping duties on that importer's entries of subject merchandise. The Department will issue appropriate assessment instructions directly to CBP within 15 days of publication of these amended final results of review.

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 these amended final results of administrative review, as provided by section 751(a) of the Tariff Act of 1930, as amended (''the Act''): (1) For the companies named above, the cash deposit rate will be the rate listed above; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a previous segment of this proceeding, the cash deposit rate will continue to be the company–specific rate published in the most recent final results in which that manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review or in any previous segment of this proceeding, but the manufacturer is, the cash deposit rate will be that established for the manufacturer of the merchandise in these final results of review or in the most recent segment of the proceeding in which that manufacturer participated; and (4) if neither the exporter nor the manufacturer is a firm covered in this review or in any previous segment of this proceeding, the cash deposit rate will be 14.74 percent, the ''All–others'' rate established in the less–than-fair–value investigation. These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 18, 2006.

David M. Spooner,

Assistant Secretaryfor Import Administration.

[FR Doc. E6–824 Filed 1–23–06; 8:45 am]

BILLING CODE 3510–DS–S

[2] Petitioners are Allied Tube and Conduit Corporation, and Wheatland Tube Company.

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent To Perform an Environmental Assessment for Increased Depleted Uranium Use at Nevada Test and Training Range, Nevada

AGENCY: Department of the Air Force (AF), Air Combat Command (ACC).

ACTION: Notice of intent to prepare an Environmental Assessment (EA) for the Increased Depleted Uranium (DU) Use at Nevada Test and Training Range (NTTR).

Authority: 42 United States Code §§ 4321–4347 40 Code of Federal Regulations (CFR) parts 1500–1508.

SUMMARY: The United States Air Force is issuing this Notice of Intent (NOI) to announce that it is conducting an environmental assessment for the proposed action for increasing the annual number of depleted uranium (DU) rounds fired by A–10 aircraft using the 30-millimeter GAU–8 Gatling gun at the Nevada Test and Training Range (NTTR), Range 63, Target 63–10. This NOI describes the Air Force's proposed scoping process and identifies the Air Force's point of contact. Target 63–10 is the Air Force's only air-to-ground target for testing and training with DU rounds.

The proposed assessment will be prepared in compliance with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321–4347), the Council on Environmental Quality NEPA regulations (40 CFR parts 1500–1508), and Air Force's Environmental Impact Analysis Process (EIAP) (Air Force Instruction 32–7061 as promulgated at 32 CFR part 989) to determine the potential environmental effects of increasing DU rounds at the NTTR.

As part of the proposal, the Air Force will analyze three alternatives: A, B, and C. Alternative A (proposed action) would increase the annual use of 30-mm DU rounds in a combat mix (CM) from an existing 9,500 to 22,800 annually. CM contains armor-piercing incendiary (API) DU rounds mixed with high explosive incendiary (HEI) rounds in a 5 to 1 ratio. Alternative A would increase the annual use of DU rounds from 7,900 to 19,000 (and HEI rounds from 1,600 to 3,800) to provide the 422 Test and Evaluation Squadron (TES) and the 66 Weapons Squadron (WPS) graduates with sufficient DU rounds to accomplish essential testing and training requirements. Alternative B would enhance testing by increasing the use of CM to a total of 31,680 rounds (26,400 DU and 5,280 HEI) at Target 63–10. This alternative would meet test and training requirements and also allow additional testing by Tactics Development & Evaluation (TD&E) and Tactics Improvement Proposals (TIP). Alternative C (no-action) would reflect no change in current operations associated with Target 63–10 whereby 9,500 CM rounds (7,900 DU and 1,600 HEI) are deployed for test and training. This number (9,500) does not provide enough rounds for effective TES testing and WPS training.

DATES: The Air Force will conduct two scoping meetings to receive public input on alternatives, concerns, and issues to be addressed in the EA and to solicit public input concerning the scope of the proposed action and alternatives. The

schedule and locations of the scoping meetings are as follows: January 31, 2006: 6:30 p.m.–8:30 p.m., Sunrise Library, 5400 Harris Avenue, Las Vegas, Nevada and February 1, 2006: 6:30 p.m.–8:30 p.m., Indian Springs Community Center, 719 West Gretta Lane, Indian Springs, Nevada.

The Air Force will accept comments at any time during the scoping period. However, to ensure the Air Force considers relevant scoping issues in a timely fashion, all comments should be forwarded to the address below no later than March 1, 2006. If during the preparation of the EA, the Air Force concludes an Environmental Impact Statement (EIS) is warranted, comments received during this scoping period will be considered in the preparation of the EIS.

FOR FURTHER INFORMATION CONTACT: Mike Estrada, Nellis Air Force Base Office of Public Affairs, 4430 Grissom Avenue, Ste 107, Nellis AFB, NV 89191, (702) 652–2750.

Lawrence Shade,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. E6–794 Filed 1–23–06; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0130]

Federal Acquisition Regulation; Information Collection; Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance (9000–0130).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate. The clearance currently expires on April 30, 2006.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before March 27, 2006.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden to the General Services Administration, Regulatory Secretariat (VIR), 1800 F Street, NW, Room 4035, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT Ms. Kimberly Marshall, Contract Policy Division, GSA, (202) 219–0986.

SUPPLEMENTARY INFORMATION:

A. Purpose

Under the Free Trade Agreements Acts of 1979, unless specifically exempted by statute or regulation, agencies are required to evaluate offers over a certain dollar limitation to supply an eligible product without regard to the restrictions of the Buy American Act or the Balance of Payments program. Offerors identify excluded end products and FTA end products on this certificate.

The contracting officer uses the information to identify the offered items which are domestic and FTA country end products so as to give these products a preference during the evaluation of offers. Items having components of unknown origin are considered to have been mined, produced, or manufactured outside the United States.

B. Annual Reporting Burden

Respondents: 1,140.
Responses Per Respondent: 5.
Annual Responses: 5,700.
Hours Per Response: .167.
Total Burden Hours: 666.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VIR), Room 4035, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0130, Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate, in all correspondence.

Dated: January 13, 2006.

Gerald Zaffos,

Director, Contract Policy Division.

[FR Doc. 06–670 Filed 1–23–06; 8:45 am]

BILLING CODE 6820–EP–S?≤

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 23, 2006.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Rachel Potter, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503 or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) 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. OMB invites public comment.

Dated: January 17, 2006.

Angela C. Arrington,

IC Clearance Official,Regulatory Information Management Services,Office of the Chief Information Officer.

Federal Student Aid

Type of Review: Extension.

Title: Direct Loan Income Contingent Repayment Plan—Consent to Disclosure of Tax Information.

Frequency: On Occasion.

Affected Public: Individuals or household.

Reporting and Recordkeeping Hour Burden:

Responses: 393,577.

Burden Hours: 78,716.

Abstract: This form is the means by which a William D. Ford Federal Direct Loan Program borrower (and, if married, the borrower's spouse) who chooses to repay under the Income Contingent Repayment Plan provides written consent for the Internal Revenue Service to disclose certain tax return information to the Department of Education and its agents for the purpose of calculating the borrower's monthly repayment amount.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 2939. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *IC DocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to the e-mail address *IC DocketMgr@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–767 Filed 1–23–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 23, 2006.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Rachel Potter, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503 or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) 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. OMB invites public comment.

Dated: January 17, 2006.

Angela C. Arrington,

IC Clearance Official,Regulatory Information Management Services,Office of the Chief Information Officer.

Federal Student Aid

Type of Review: Extension.

Title: William D. Ford Federal Direct Loan Program Statutory Forbearance Forms.

Frequency: On Occasion.

Affected Public: Individuals or household.

Reporting and Recordkeeping Hour Burden:

Responses: 5,115.

Burden Hours: 1,023.

Abstract: Borrowers who receive loans through the William D. Ford Federal Direct Loan Program will use this form to agree to statutory forbearances on their loans.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 2936. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *IC DocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to the e-mail address *IC DocketMgr@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–769 Filed 1–23–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 23, 2006.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Rachel Potter, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503 or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested

Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) 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. OMB invites public comment.

Dated: January 17, 2006.

Angela C. Arrington,

IC Clearance Official,Regulatory Information Management Services,Office of the Chief Information Officer.

Federal Student Aid

Type of Review: Revision.

Title: Direct Loan Income Contingent Repayment Plan Alternative Documentation of Income.

Frequency: On Occasion.

Affected Public: Individuals or household.

Reporting and Recordkeeping Hour Burden:

Responses: 863,357.

Burden Hours: 285,007.

Abstract: A William D. Ford Federal Direct Loan Program borrower (and, if married, the borrower's spouse) who chooses to repay under the Income Contingent Repayment Plan uses this form to submit alternative documentation of income if the borrower's adjusted gross income is not available or does not accurately reflect the borrower's current income.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 2937. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *IC DocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to the e-mail address *IC DocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–770 Filed 1–23–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 23, 2006.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Rachel Potter, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503 or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) Title; (3) 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. OMB invites public comment.

Dated: January 18, 2006,

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer.

Office of Elementary and Secondary Education

Type of Review: Revision.

Title: Consolidated State Application/Consolidated State Annual Report.

Frequency: Annually.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 52.

Burden Hours: 7,800.

Abstract: This information collection package describes the proposed criteria and procedures that govern the consolidated State application under which State educational agencies will apply to obtain funds for implementing ESEA programs. The option of submitting a consolidated application for obtaining federal formula program grant funds is provided for in the reauthorized ESEA (No Child Left Behind—NCLB) sections 9301–9306. This information collection package will guide the States in identifying the information and data required in the application.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 2886. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *IC DocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to the e-mail address *IC DocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information

Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–811 Filed 1–23–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 23, 2006.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Rachel Potter, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503 or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) Title; (3) 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. OMB invites public comment.

Dated: January 18, 2006.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Office.

Federal Student Aid

Type of Review: Extension.

Title: Federal Stafford Loan Master Promissory Note.

Frequency: On Occasion.

Affected Public: Individuals or household.

Reporting and Recordkeeping Hour Burden:

Responses: 2,959,380.

Burden Hours: 2,219,535.

Abstract: The Federal Stafford Loan Master Promissory Note is the means by which an eligible student borrower promises to repay a Federal Stafford Loan.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 2898. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *IC DocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to the e-mail address *IC DocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–812 Filed 1–23–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No. 84.359A/B]

Office of Elementary and Secondary Education; Early Reading First Program; Correction; Notice Correcting the Deadline for Transmittal of Pre-Applications Date

ACTION: Correction; Notice correcting the deadline for Transmittal of Pre-Applications Date.

SUMMARY: We correct the *Deadline for Transmittal of Pre-Applications* in the notice published on January 18, 2006 (71 FR 2916).

SUPPLEMENTARY INFORMATION: On January 18, 2006, we published a notice in the **Federal Register** inviting applications for new awards for fiscal year 2006 for the Early Reading First program. The date listed under *Deadline for Transmittal of Pre-Applications* was incorrect, in that it falls on a Federal holiday. The correct *Deadline for Transmittal of Pre-Applications* date is February 21, 2006.

FOR FURTHER INFORMATION CONTACT: Jill Stewart, U.S. Department of Education, 400 Maryland Avenue, SW., room 3C136, Washington, DC 20202–6132. Telephone: (202) 260–2533 or by e-mail: *Jill.Stewart@ed.gov* or Rebecca Haynes, U.S. Department of Education, 400 Maryland Avenue, SW., room 3C138, Washington, DC 20202–6132. Telephone: (202) 260–0968 or by e-mail: *Rebecca.Haynes@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact persons listed in this section.

Electronic Access to This Document

You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

For additional program information call one of the program contact persons listed in this section between the hours of 8 a.m. and 5 p.m., Eastern Time, Monday through Friday.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *www.gpoaccess.gov/nara/index.html.*

Dated: January 19, 2006.

Henry L. Johnson,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. E6–827 Filed 1–23–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Postsecondary Education; Overview Information; Developing Hispanic-Serving Institutions (HSI) Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2006

Catalog of Federal Domestic Assistance (CFDA) *Number:* 84.031S.

DATES: *Applications Available:* January 24, 2006.

Deadline for Transmittal of Applications: March 10, 2006.

Deadline for Intergovernmental Review: March 27, 2006.

Eligible Applicants: Institutions of higher education (IHEs) that qualify as eligible HSIs are eligible to apply for new Individual Development Grants and Cooperative Arrangement Development Grants under the HSI Program. To be an eligible HSI, an IHE must—

(1) Be accredited or preaccredited by a nationally recognized accrediting agency or association that the Secretary has determined to be a reliable authority as to the quality of education or training offered;

(2) Be legally authorized by the State in which it is located to be a junior college or to provide an educational program for which it awards a bachelor's degree;

(3) Be designated as an ''eligible institution'' by demonstrating that it: (A) Has an enrollment of needy students as described in 34 CFR 606.3; and (B) has low average educational and general expenditures per full-time equivalent (FTE) undergraduate student as described in 34 CFR 606.4;

(4) At the time of application, have an enrollment of undergraduate FTE students that is at least 25 percent Hispanic students; and

(5) Provide assurances that not less than 50 percent of its Hispanic students are low-income individuals.

For purposes of making the determinations described in paragraphs (4) and (5) above, IHEs shall use student enrollments for the fall 2005 academic year.

The Notice Inviting Applications for Designation as Eligible Institutions for FY 2006 was published in the **Federal Register** on December 16, 2005 (70 FR 74781). The HSI eligibility requirements are in 34 CFR 606.2 through 606.5 and can be accessed from the following Web site: *http://www.access.gpo.gov/nara/cfr/waisidx_01/34cfr606_01.html.*

Relationship Between HSI and Title III, Part A Programs

Note 1: A grantee under the HSI Program, which is authorized by Title V of the Higher Education Act of 1965, as amended (HEA), may not receive a grant under any HEA, Title III, Part A Program. The Title III, Part A Programs include: the Strengthening Institutions Program, the American Indian Tribally Controlled Colleges and Universities Program; and the Alaska Native and Native Hawaiian-Serving Institutions Programs. Further, a current HSI Program grantee may not give up its HSI grant in order to receive a grant under any Title III, Part A Program.

Note 2: An eligible HSI that does not fall within the limitation described in Note 1, *i.e.*, is not a current grantee under the HSI Program, may apply for a FY 2006 grant under all Title III, Part A Programs for which it is eligible, as well as under the HSI Program. However, a successful applicant may receive only one grant.

Note 3: An eligible HSI that previously received a five-year Individual Development Grant under the HSI Program must wait for two years after the date the five-year grant ended, including any time extensions the grant may have received, to apply for another Individual Development Grant under the HSI Program.

Note 4: An eligible HSI that submits more than one application may only be awarded one Individual Development Grant or one Cooperative Arrangement Development Grant in a fiscal year. Furthermore, we will not award a second Cooperative Arrangement Development Grant to an otherwise eligible HSI for the same award year as the institution's existing Cooperative Arrangement Development Grant award.

Estimated Available Funds: $20,433,000.

Estimated Range of Awards: Individual Development Grant: $300,000–$575,000. Cooperative Arrangement Development Grant: $400,000–$700,000.

Estimated Average Size of Awards: Individual Development Grant: $500,000. Cooperative Arrangement Development Grant: $600,000.

Maximum Awards: Individual Development Grant: $575,000 per year; Cooperative Arrangement Development Grant: $700,000 per year.

We will not fund any application at an amount exceeding the maximum amounts specified above for a single budget period of 12 months. We may choose not to further consider or review applications with budgets that exceed the maximum amounts specified above, if we conclude, during our initial review of the application, that the proposed goals and objectives cannot be obtained with the specified maximum amount.

Estimated Number of Awards: Individual Development Awards: 22. Cooperative Arrangement Development Awards: 14.

Note: The Department is not bound by any estimates in this notice. Applicants should periodically check the HSI Program Web site for further information. The address is: *http://www.ed.gov/programs/idueshsi/index.html.*

Project Period: Up to 60 months.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The HSI Program provides grants to assist HSIs to expand educational opportunities for, and improve the academic attainment of, Hispanic students. The HSI Program grants also enable HSIs to expand and enhance their academic offerings, program quality, and institutional stability.

Program Authority: 20 U.S.C. 1101–1101d, 1103–1103g.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 81, 82, 84, 85, 86, 97, 98, and 99. (b) The regulations for this program in 34 CFR part 606.

II. Award Information

Type of Award: Discretionary grant. Five-year Individual Development Grants and Five-year Cooperative Arrangement Development Grants will be awarded in FY 2006. Planning grants will not be awarded in FY 2006.

Estimated Available Funds: $20,433,000.

Estimated Range of Awards: Individual Development Grant: $300,000–$575,000. Cooperative Arrangement Development Grant: $400,000–$700,000.

Estimated Average Size of Awards: Individual Development Grant: $500,000. Cooperative Arrangement Development Grant: $600,000.

Maximum Awards: Individual Development Grant: $575,000. Cooperative Arrangement Development Grant: $700,000.

We will not fund any application at an amount exceeding the maximum amounts specified above for a single budget period of 12 months. We may choose not to further consider or review applications with budgets that exceed the maximum amounts specified above, if we conclude, during our initial review of the application, that the proposed goals and objectives cannot be obtained with the specified maximum amount.

Estimated Number of Awards: Individual Development Awards: 22. Cooperative Arrangement Development Awards: 14.

Note: The Department is not bound by any estimates in this notice. Applicants should periodically check the HSI Program Web site for further information. The address is: *http://www.ed.gov/programs/idueshsi/index.html.*

Project Period: Up to 60 months.

III. Eligibility Information

Eligible Applicants: IHEs that qualify as eligible HSIs are eligible to apply for new Individual Development Grants and Cooperative Arrangement Development Grants under the HSI Program. To be an eligible HSI, an IHE must—

(1) Be accredited or preaccredited by a nationally recognized accrediting agency or association that the Secretary has determined to be a reliable authority as to the quality of education or training offered;

(2) Be legally authorized by the State in which it is located to be a junior college or to provide an educational program for which it awards a bachelor's degree;

(3) Be designated as an ''eligible institution'' by demonstrating that it: (A) Has an enrollment of needy students as described in 34 CFR 606.3; and (B) has low average educational and general expenditures per FTE undergraduate student as described in 34 CFR 606.4;

(4) At the time of application, have an enrollment of undergraduate FTE students that is at least 25 percent Hispanic students; and

(5) Provide assurances that not less than 50 percent of its Hispanic students are low-income individuals.

For purposes of making the determinations described in paragraphs (4) and (5) above, IHEs shall use student enrollments for the fall 2005 academic year.

The Notice Inviting Applications for Designation as Eligible Institutions for FY 2006 was published in the **Federal Register** on December 16, 2005 (70 FR 74781). The HSI eligibility requirements are in 34 CFR 606.2 through 606.5 and can be accessed from the following Web site: *http://www.access.gpo.gov/nara/cfr/waisidx_01/34cfr606_01.html.*

Relationship Between HSI and Title III, Part A Programs

Note 1: A grantee under the HSI Program, which is authorized by Title V of the HEA, may not receive a grant under any HEA, Title III, Part A Program. The Title III, Part A Programs include: the Strengthening Institutions Program; the American Indian Tribally Controlled Colleges and Universities Program; and the Alaska Native and Native Hawaiian-Serving Institutions Programs. Further, a current HSI Program grantee may not give up its HSI grant in order to receive a grant under any Title III, Part A Program.

Note 2: An eligible HSI that does not fall within the limitation described in Note 1, *i.e.*, is not a current grantee under the HSI Program, may apply for a FY 2006 grant under all Title III, Part A Programs for which it is eligible, as well as under the HSI Program. However, a successful applicant may receive only one grant.

Note 3: An eligible HSI that previously received a five-year Individual Development Grant under the HSI Program must wait for two years after the date the five-year grant ended, including any time extensions the grant may have received, to apply for another Individual Development Grant under the HSI Program.

Note 4: An eligible HSI that submits more than one application may only be awarded one Individual Development Grant or one Cooperative Arrangement Development Grant in a fiscal year. Furthermore, we will not award a second Cooperative Arrangement Development Grant to an otherwise eligible HSI for the same award year as the institution's existing Cooperative Arrangement Development Grant award.

2. *Cost Sharing or Matching:* There are no cost sharing or matching requirements, unless the grantee uses a portion of its grant for establishing or improving an endowment fund. If a grantee uses a portion of its grant for endowment fund purposes, it must match those grant funds with non-Federal funds. (20 U.S.C. 1101c).

IV. Application and Submission Information

1. *Address to Request Application Package:* J. Alexander Hamilton, U.S. Department of Education, 1990 K Street, NW., 6th Floor, Washington, DC 20006–8513. Telephone: (202) 502–7583 or by e-mail: *Josephine.Hamilton@ed.gov*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain a copy of the application package in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) by contacting the program contact person listed in this section.

2. *Content and Form of Application Submission:*

a. Applicants must provide, as an attachment to the application, the documentation the institution relied upon in determining that, for the fall 2005 academic year, at least 25 percent of the institution's undergraduate FTE students are Hispanic, and at least 50 percent of the enrolled Hispanic students are low-income individuals.

Note: The 25 percent requirement applies only to undergraduate Hispanic students and is calculated based upon FTE students. The 50 percent low-income requirement includes the institution's total enrollment of Hispanic students and is calculated based upon head count. Instructions for formatting and submitting the verification documentation to *Grants.gov* are in the application package.

b. Additional requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program.

Page Limits: The program narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We have established mandatory page limits for both the Individual Development Grant and the Cooperative Arrangement Development Grant applications. You must limit the section of the narrative that addresses the selection criteria to no more than 50 pages for the Individual Development Grant application and 70 pages for the Cooperative Arrangement Development Grant application, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1 inch margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, except titles, headings, footnotes, quotations, references, captions and all text in charts, tables, and graphs.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. Applications submitted in any other font (including Times Roman and Arial Narrow) will not be accepted.
- Use font size 12.

The page limit does not apply to Part I, the application for federal assistance face sheet (SF 424); the supplemental information form required by the Department of Education; Part II, the budget information summary form (ED Form 524); and Part IV, the assurances and certifications. The page limit also does not apply to a table of contents or the program abstract. If you include any attachments or appendices other than those specifically requested, these items will be counted as part of the program narrative (Part III) for purposes of the page limit requirement. You must include your complete response to the selection criteria in the program narrative.

We will reject your application if—

- You apply these standards and exceed the page limit; or
- You apply other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:* Applications Available: January 24, 2006. Deadline for Transmittal of Applications: March 10, 2006.

Applications for grants under this program competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically or by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Deadline for Intergovernmental Review: March 27, 2006.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference the regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

• *Applicability of Executive Order 13202.* Applicants that apply for construction funds under the HSI Program must comply with Executive Order 13202, signed by President Bush on February 17, 2001 and amended on April 6, 2001. This Executive order provides that recipients of Federal construction funds may not ''require or prohibit bidders, offerors, contractors, or subcontractors to enter into or adhere to agreements with one or more labor organizations, on the same or other construction project(s)'' or ''otherwise discriminate against bidders, offerors, contractors, or subcontractors for becoming or refusing to become or remain signatories or otherwise adhere to agreements with one or more labor organizations, on the same or other construction project(s).'' However, the Executive order does not prohibit contractors or subcontractors from voluntarily entering into these agreements. Projects funded under this program that include construction activity will be provided a copy of this Executive order and grantees will be asked to certify that they will adhere to it.

6. *Other Submission Requirements:* Applications for grants under this program competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the HSI Program (CFDA Number 84.031S) must be submitted electronically using the Grants.gov Apply site at: *http://www.grants.gov*. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for the HSI Program at: *http://www.grants.gov*. You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search.

Please note the following:

• When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

• Applications received by Grants.gov are time and date stamped. Your application must be fully uploaded and submitted, and must be date/time stamped by the Grants.gov system no later than 4:30 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not consider your application if it is date/time stamped by the Grants.gov system later than 4:30 p.m., Washington, DC time, on the application deadline date. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date/time stamped by the Grants.gov system after 4:30 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

• You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this program competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov at *http://e-Grants.ed.gov/help/GrantsgovSubmissionProcedures.pdf*.

• To submit your application via Grants.gov, you must complete all of the steps in the Grants.gov registration process (see *http://www.Grants.gov/GetStarted*). These steps include (1) registering your organization, (2) registering yourself as an Authorized Organization Representative (AOR), and (3) getting authorized as an AOR by your organization. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see *http://www.grants.gov/assets/GrantsgovCoBrandBrochure8X11.pdf*). You also must provide on your application the same D–U–N–S Number used with this registration. Please note that the registration process may take five or more business days to complete, and you must have completed all registration steps to allow you to successfully submit an application via Grants.gov.

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

• You must submit all documents electronically, including all information typically included on the Application for Federal Education Assistance (SF 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. You must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified above or submit a password protected file, we will not review that material.

• Your electronic application must comply with any page limit requirements described in this notice.

• After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The Department will retrieve your application from Grants.gov and send you a second confirmation by e-mail that will include

a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically, or by hand delivery. You also may mail your application by following the mailing instructions as described elsewhere in this notice. If you submit an application after 4:30 p.m., Washington, DC time, on the deadline date, please contact the person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT**, and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number (if available). We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: Extensions referred to in this section apply only to the unavailability of or technical problems with the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the Grants.gov system; and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: J. Alexander Hamilton, U.S. Department of Education, 1990 K Street, NW., room 6052, Washington, DC 20006–8513 FAX: (202) 502–7861.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 84.031S),
400 Maryland Avenue, SW.,
Washington, DC 20202–4260 or,

By mail through a commercial carrier:

U.S. Department of Education,
Application Control Center—Stop 4260, Attention: (CFDA Number 84.031S), 7100 Old Landover Road,
Landover, MD 20785–1506.

Regardless of which address you use, you must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark,

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service,

(3) A dated shipping label, invoice, or receipt from a commercial carrier, or

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark, or

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 84.031S),
550 12th Street, SW., Room 7041,
Potomac Center Plaza, Washington,
DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department:

(1) You must indicate on the envelope and—if not provided by the Department—in Item 4 of the Application for Federal Education Assistance (SF 424) the CFDA number—and suffix letter, if any—of the competition under which you are submitting your application.

(2) The Application Control Center will mail a grant application receipt acknowledgment to you. If you do not receive the grant application receipt acknowledgment within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are in 34 CFR 606.22(a)–(g). Applicants must address each of the following selection criteria (separately for each proposed activity). The total weight of the selection criteria is 100 points; the weight of each criterion is noted in parentheses.

(a) Quality of The Applicant's Comprehensive Development Plan (Total 25 Points).

(b) Quality of Activity Objectives (Total 15 Points).

(c) Quality of Implementation Strategy (Total 20 Points).

(d) Quality of Key Personnel (Total 7 Points).

(e) Quality of Project Management Plan (Total 10 Points).

(f) Quality of Evaluation Plan (Total 15 Points).

(g) Budget (Total 8 Points).

2. *Review and Selection Process:* Tiebreaker for Development Grants. In tie-breaking situations for development grants described in 34 CFR 606.23(b), the HSI Program regulations require that we award one additional point to an application from an IHE that has an endowment fund for which the market value per FTE student is less than the comparable average per FTE student at a similar type of IHE. We also award one additional point to an application from an IHE that had expenditures for library materials per FTE student that are less than the comparable average per FTE student at a similar type IHE.

For the purpose of these funding considerations, we use 2003–2004 data.

If a tie remains after applying the tiebreaker mechanism above, priority will be given in the case of applicants for: (a) Individual Development Grants to applicants that addressed the statutory priority found in section 511(d) of the HEA; and (b) Cooperative Arrangement Development Grants to applicants in accordance with section 514(b) of the HEA, if the Secretary determines that the cooperative arrangement is geographically and economically sound or will benefit the applicant HSI.

If a tie still remains after applying the additional point(s), and the relevant statutory priority, we will determine the ranking of applicants based on the lowest endowment values per FTE student.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may also notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as specified by the Secretary in 34 CFR 75.118, 34 CFR 75.720, and in 34 CFR 606.31.

4. *Performance Measures:* The Secretary has established the following key performance measures for assessing the effectiveness of the HSI Program: (1) The percentage of full-time undergraduate students who were in their first year of postsecondary enrollment in the previous year and are enrolled in the current year at the same institution; (2) The percentage of students enrolled at 4-year HSIs graduating within 6 years of enrollment; and (3) The percentage of students enrolled at 2-year HSIs graduating within 3 years of enrollment.

VII. Agency Contacts

For Further Information Contact: J. Alexander Hamilton, U.S. Department of Education, 1990 K Street, NW., 6th Floor, Washington, DC 20006–8513. Telephone: (202) 502–7583 or by e-mail: *Josephine.Hamilton@ed.gov* or Carnisia Proctor, Telephone: (202) 502–7606 or by e-mail: *Carnisia.Proctor@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact person listed in this section.

VIII. Other Information

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: January 19, 2006.

Sally L. Stroup,

Assistant Secretary for Postsecondary Education.

[FR Doc. E6–829 Filed 1–23–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Amended Record of Decision: Savannah River Site Salt Processing Alternatives

AGENCY: Department of Energy (DOE).

ACTION: Amended record of decision.

SUMMARY: The Department of Energy (DOE), pursuant to 10 CFR 1021.315, is amending its *Record of Decision: Savannah River Site Salt Processing Alternatives* issued on October 17, 2001 (66 FR 52752). At that time the Department decided to implement the Caustic Side Solvent Extraction (CSSX) technology, one of the alternative technologies evaluated in DOE/EIS–0082–S2 (Savannah River Site Salt Processing Alternatives Final Supplemental Environmental Impact Statement (SPA SEIS), June 2001) for separation of the high-activity fraction from the low-activity fraction of Savannah River Site (SRS) salt wastes. DOE has initiated design of the Salt Waste Processing Facility (SWPF), which will house the CSSX technology. Now, using technologies described in the SPA SEIS, DOE has decided to change the processing and disposition pathway for a fraction of the low activity salt waste currently stored in the F- and H-Area tank farms. This action is called Interim Salt Processing. When the SWPF becomes operational, the remaining (and by far the majority) salt waste will be processed through the SWPF using the CSSX technology as described in the SPA SEIS; this action is called High Capacity Salt Processing.

DOE will proceed with this interim approach because doing so will enable DOE to continue uninterrupted use of the Defense Waste Processing Facility (DWPF) to vitrify higher activity sludge waste for disposal at a geologic repository for spent nuclear fuel and high-level waste. It will also allow DOE to use SWPF at higher capacity as soon as it comes on line. This will allow DOE to complete cleanup and closure of the tanks years earlier than would otherwise be the case. That, in turn, will reduce the time during which the tanks—including some that do not have full secondary containment and have a known history of leak sites—continue to store liquid radioactive waste. Finally, Interim Salt Processing will make more

tank space available for routine operations, thereby reducing the number of transfers among tanks and increasing the safety of operations. Therefore, Interim Salt Processing will accelerate the reduction of potential risk to the environment, the public, and workers.

DOE has prepared a Supplement Analysis (SA), Salt Processing Alternatives at the Savannah River Site (DOE/EIS–0082–S2–SA–01), in accordance with DOE National Environmental Policy Act (NEPA) regulations (10 CFR 1021.314) to determine whether implementation of Interim Salt Processing is a substantial change to the selected CSSX processing of salt waste or whether there are significant new circumstances or information relevant to environmental concerns such that a supplement to the SPA SEIS or a new EIS would be needed. Based on the SA, DOE has determined that a supplement to the SPA SEIS or a new EIS is not needed.

FOR FURTHER INFORMATION CONTACT: Copies of the SPA SEIS and the 2001 Record of Decision are available on DOE's NEPA Web site at: *http://www.eh.doe.gov/nepa*. Copies of this amended Record of Decision, and the SA, will be available on DOE's NEPA Web site at: *http://www.eh.doe.gov/nepa* under DOE NEPA Documents. To request copies of these documents, please contact: The Center for Environmental Management Information, P.O. Box 23769, Washington, DC 20026–3769. Telephone: 800–736–3282 (in Washington, DC: 202–863–5084).

For further information regarding the processing and disposal of salt waste at the Savannah River Site, or to obtain copies of the SA discussed herein, or this amended Record of Decision, contact: Mr. Andrew R. Grainger, Savannah River Operations Office, U.S. Department of Energy, P.O. Box B, Aiken, SC 29802. Telephone: 803–952–8001. E-mail: *drew.grainger@srs.gov.*

For information on DOE's NEPA process, contact: Ms. Carol Borgstrom, Director, Office of NEPA Policy and Compliance, EH–42, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–0119. Telephone 202–586–4600, or leave a message at 800–472–2756.

SUPPLEMENTARY INFORMATION:

I. Background

DOE evaluated the environmental impacts of construction and operation of four alternative technologies for salt waste processing in the SPA SEIS. First, the concentrated supernate solution and solid saltcake (including the interstitial liquid) would be combined. The four salt processing technology alternatives considered in the SPA EIS all include initial separation of actinides (including plutonium and uranium) present in the salt solution by sorption on monosodium titanate (MST), followed by removal by filtration. The separated actinides would be sent to the DWPF for vitrification along with the sludge portion of the tank waste, which would not be processed through the salt processing facility. The remaining salt solution, which would have high concentrations of cesium (Cs) but very low concentrations of actinides after the MST step, would be further processed to remove most of the Cs.

The alternatives described in the SPA SEIS differ in the approach for removal of radioactive Cs from the salt solution. For each action alternative except Direct Disposal in Grout, most of the Cs would be extracted from the salt solution and incorporated into a vitrified waste form at the DWPF, along with the sludge portion of the tank waste and the actinides extracted in the MST step. The remaining low-activity salt waste stream would be sent to the Saltstone Production Facility, where it would be combined with grout in a homogeneous mixture and sent to the Saltstone Disposal Facility (also referred to as the Saltstone Vaults) for onsite disposal. Under the SEIS, all action alternatives but Direct Disposal in Grout would meet current permit conditions equivalent to Class A low-level waste. The Direct Disposal in Grout alternative would not meet the permit conditions due to high Cs concentrations. Under all action alternatives, the actinide concentration of the salt waste disposed in the Saltstone Disposal Facility would not exceed the Nuclear Regulatory Commission (NRC) concentration limits for Class A low-level waste, and would be about 10 nanocuries per gram.

DOE issued the Final SPA SEIS in June 2001 and in October 2001 DOE issued a Record of Decision selecting the preferred alternative described in the Final SPA SEIS—CSSX, with MST for removal of actinides—as the treatment technology for salt waste. DOE is currently designing the SWPF which will house the CSSX and MST treatment technologies.

The disposal of saltstone waste in the Saltstone Disposal Facility is subject to the requirements of section 3116 of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005 (NDAA). NDAA section 3116 authorizes the Secretary of Energy, in consultation with the NRC, to determine that certain waste from reprocessing is not high-level waste and that disposal in a geologic repository is not required, if it meets certain criteria. DOE prepared a Draft section 3116 Determination for Salt Waste Disposal at the Savannah River Site in February 2005, and consulted with the NRC pursuant to section 3116 of the NDAA. Although not required by section 3116, DOE made the draft 3116 Determination available for public review concurrent with DOE's consultation with the NRC.

The NRC consultation process has been completed. On December 28, 2005, the NRC issued its Technical Evaluation Report of the U.S. Department of Energy Draft section 3116 Waste Determination for Salt Waste Disposal (TER). The TER presents information on DOE's salt waste processing strategy, the applicable review criteria, and the NRC's review approach, as well as the NRC's analysis and conclusions with respect to whether there is reasonable assurance that DOE's proposed approach can meet the applicable requirements of the NDAA for determining that waste is not high-level waste. As noted in its executive summary, ''Based on the information provided by DOE to the NRC * * *, the NRC staff has concluded that there is reasonable assurance that the applicable criteria of the NDAA can be met provided certain assumptions made in DOE's analyses are verified via monitoring.'' [1]

DOE considered the NRC's TER, as well as the public comments on the Draft section 3116 Waste Determination, before issuing the section 3116 Waste Determination in January 2006. DOE also considered whether the comments on the Draft section 3116 Waste Determination raise issues or provide information that would affect the environmental discussion in the Salt Processing Alternatives SA and has determined that they do not.

In the section 3116 Determination for Salt Waste Disposal at the Savannah River Site DOE concluded that, as demonstrated in the section 3116 Determination for Salt Waste Disposal at the Savannah River Site and in consideration of DOE's consultation with the NRC, the solidified low-activity salt waste is not high-level waste and may be disposed of in the Saltstone Disposal Facility at SRS. DOE also stated that DOE will continue to take actions (such as sampling, monitoring, and ensuring vault inventory limits) to confirm the ongoing validity of the Determination and to explore additional

[1] NRC also made a number of observations regarding DOE's analysis. DOE addressed several key NRC observations in the Section 3116 Determination for Salt Waste Disposal at the Savannah River Site.

actions to further enhance the protection of workers, the public, and the environment.

Interim Salt Processing and SWPF Operation [2]

Since issuing the SPA SEIS and ROD, DOE has further considered options to maintain sufficient tank space to continue to vitrify sludge waste in the DWPF in the interim before the SWPF is operational. Continuing to operate DWPF will allow DOE to remove and vitrify sludge waste; prepare salt waste for treatment and disposal, and empty waste tanks so they may be closed. All of these actions will contribute to DOE's ability to continue to reduce the human health and environmental risk inherent in storage of high volumes of liquid radioactive waste.

DOE will now process the salt waste using a two-phase, three-part process. The first phase (herein referred to as Interim Salt Processing) will involve two parts to treat some of the lower activity salt waste: (1) Beginning in 2006, processing of a minimal amount of the lowest activity salt waste through a process involving deliquification, dissolution, and adjustment (DDA) of the waste; and (2) beginning in 2007, processing a minimal amount of additional salt waste with slightly higher activity levels using an Actinide Removal Process (ARP) and a Modular CSSX Unit (MCU), following deliquification, dissolution, and adjustment of saltcake. The second and longer term phase, herein referred to as High Capacity Salt Processing, is identical to the CSSX technology as presented in the SPA SEIS and will, beginning in 2011, separate and process the remaining (and by far the majority) of the salt waste using the SWPF (augmented as necessary by ARP). The second phase will begin as soon as SWPF is constructed, permitted by the State of South Carolina, and becomes operational. The first, interim processing phase will cease at that time (except that ARP could be used as necessary to augment SWPF).[3]

About 33.8 million gallons (Mgal) of salt waste are currently stored in underground waste storage tanks at SRS. This waste, along with future salt waste forecasted to be sent to the tank farms, will be processed through DDA, ARP/MCU, and the SWPF. DOE estimated in preparing the Section 3116 Determination that an additional 41.3 Mgal of unconcentrated salt waste would have been received by the Tank Farms between December 1, 2004, and the completion of salt waste processing. After both liquid removal by processing through the Tank Farm evaporator systems and later additions of liquid for saltcake dissolution and chemistry adjustments required for processing, approximately 84 Mgal (5.9 Mgal existing salt waste through the DDA process, 1.0 Mgal future salt waste through the DDA process, 2.1 Mgal existing and future salt waste through ARP/MCU, 69.1 Mgal existing salt waste through SWPF, and 5.9 Mgal future salt waste through SWPF) of salt solution will be processed by Interim Salt Processing and High Capacity Salt Processing resulting in approximately 168 Mgal of grout output from the Saltstone Production Facility to be disposed of in the Saltstone Disposal Facility.

In terms of curies, implementation of Interim Salt Processing followed by High Capacity Salt Processing will result in onsite disposal of 3.0 to 5.0 million curies (MCi), with the majority (about 2.8 MCi of 3.0 MCi) resulting from Interim Salt Processing, in the Saltstone Disposal Facility. This represents 1.3 to 2.2 percent of the approximately 223 MCi in the salt waste. DOE's current estimate is that 3.0 MCi, or 1.3 percent of the total will be disposed of in the Saltstone Disposal Facility, and 3.0 MCi is used in this document. The higher number of 5 MCi represents uncertainties in the radiological characterization of the salt waste.

Deliquification, Dissolution, and Adjustment, Actinide Removal Process, and Modular CSSX Unit

These facilities and processes are described in the Salt Processing Alternatives SA, and in greater detail in DOE's section 3116 Determination for Salt Waste Disposal at the Savannah River Site. The DDA process will be the first interim process used and will be used to process some of the lowest activity salt waste from 2006 until 2011 when the SWPF begins operation. The DDA process will also be used to prepare waste feed streams for the ARP and MCU and will operate in parallel with those facilities.

In 2007, ARP and MCU operations will be initiated to process slightly higher activity salt waste. ARP and MCU will use processes described in the SPA SEIS (MST treatment and CSSX), the same technologies that will be incorporated in the SWPF, which will process about 98.7 percent of the 223 million curies in salt waste.

The ARP will be comprised of the actinide removal process that was described as part of the pilot plant, which also included a low-capacity CSSX capability, in the SPA SEIS. In order to take advantage of existing infrastructure and minimize construction costs, DOE will modify existing SRS facilities 512–S (formerly the Late Wash Facility) and 241–96H (formerly the filter building portion of the In-Tank Precipitation facility). The MCU will house a low-capacity CSSX technology, similar to the pilot plant described in the SPA SEIS. The MCU is being constructed in the former cold feeds area of the In-Tank Precipitation facility. The SA provides further details of the new and existing facilities and processes that will be used for Interim Salt Processing.

Regulatory Requirements

A modification to the Saltstone Disposal Facility Industrial Solid Waste Landfill (ISWL) permit, issued by the South Carolina Department of Health and Environmental Control (SCDHEC), will be required prior to implementation of Interim Salt Processing. The current Saltstone Disposal Facility ISWL permit authorizes disposal of waste with radionuclide concentrations comparable to Class A low-level waste limits (10 nCi/g) as defined in NRC regulations at

[2] The numbers and percentages in this Amended Record of Decision are either rounded numbers and percentages or are DOE's best estimates at this time. The numbers, percentages, and dates in this Amended Record of Decision should be viewed as approximate numbers, percentages, and dates.

[3] The start date for SWPF operations has been delayed (from 2009 to 2011) to allow for modification of the SWPF preliminary design to incorporate a higher degree of performance category (PC) in the confinement barriers necessary for worker protection during natural phenomena hazard events. The Defense Nuclear Facilities Safety Board initially identified concerns related to the PC designations of the SWPF in August, 2004. DOE agreed in November, 2005, to modify the SWPF design after extensive analysis and review, resulting in an approximate two year delay in the planned startup of SWPF. DOE anticipates that it will continue to explore possible ways to improve the schedule for design and construction of the SWPF. It remains DOE's goal to complete processing of salt waste through the SWPF by 2019 although this date may need to be modified in the future. Despite this projected delay, DOE will not increase the quantity of waste (total curies) to be disposed of in the Saltstone Disposal Facility, nor increase the quantities (curies) processed with interim processes or SWPF from those described here and in the Draft Section 3116 Determination for Salt Waste Disposal at the Savannah River Site and the Section 3116 Determination for Salt Waste Disposal at the Savannah River Site. Therefore, the date change does not affect the analyses in the Section 3116 Determination for Salt Waste Disposal at the Savannah River Site, its supporting documents, or the NRC consultation. The modified schedule is reflected in the Section 3116 Determination for Salt Waste Disposal at the Savannah River. However, the technical and programmatic documents that are referenced by the Section 3116 Determination for Salt Waste Disposal at the Savannah River Site have not been updated to reflect this new date because the schedule change did not occur until after those documents were completed.

10 CFR 61.55. SCDHEC under its State wastewater permitting authority issued the permit. The permit requires DOE to notify SCDHEC if the characteristics of wastes to be disposed in the Saltstone Disposal Facility would change, as will be the case with the higher concentrations of radionuclides (about 0.2 Ci/gal rather than about 0.1 Ci/gal, and about 41 nCi/g actinides rather than less than 10 nCi/g) in saltstone that will be disposed when DOE implements Interim Salt Processing. DOE has submitted a request for a modification to the Saltstone Disposal Facility ISWL permit. The requested modification would cover waste with concentrations less than the NRC Class C limits (100 nCi/gm).

II. Decision

DOE has decided to implement Interim Salt Processing, followed by High Capacity Salt Processing using the CSSX technology when the SWPF becomes operational. DOE will change the processing and disposition pathway for a fraction (about 1.3 percent, or about 3.0 MCi) of the salt waste currently stored in the F- and H-Area tank farms. DOE will use the DDA process to segregate supernate and interstitial liquid from saltcake in order to send salt waste with low curie content (about 2.5 MCi, or about 6.9 Mgal) to the Saltstone Production Facility, where it will be combined with chemicals to form a grout matrix and sent to the Saltstone Disposal Facility. The waste processed with DDA will, after solidification, have an average Cs concentration of about 0.2 Ci/gal and actinide concentration of about 41 nCi/g. DOE will also use the DDA process to dispose of 0.24 Mgal of relatively low activity salt solution currently stored in Tank 48. DOE will process this waste without removal of radionuclides by combining the stream with another salt waste stream, currently planned to be the low-activity liquid recycle waste stream from the DWPF. About 2.1 Mgal of salt waste with slightly higher curie content will be prepared for processing through the ARP and MCU; about 0.3 MCi, or about 2.1 Mgal, will be disposed of in the Saltstone Disposal Facility. When SWPF becomes operational in about 2011 the CSSX technology will be used to process the inventory of salt waste that was not processed during interim salt processing. DOE expects to process about 98.7 percent (about 220 MCi) of the salt waste inventory using the CSSX technology as described in the SPA SEIS. After processing in the SWPF waste sent to the Saltstone Disposal Facility will have a Cs concentration of about 0.1 Ci/gal and actinide concentration of less than 10 nCi/g.

III. Basis for the Decision

DOE has initiated design of the Salt Waste Processing Facility (SWPF), which will house the CSSX technology selected in the Record of Decision. Now, using technologies described in the SPA SEIS, DOE has decided to change the processing and disposition pathway for a fraction of the salt waste currently stored in the F- and H-Area tank farms. This action is called Interim Salt Processing. When the SWPF becomes operational, the remaining salt waste will be processed using High Capacity Salt Processing through the SWPF using the CSSX technology as described in the SPA SEIS.

If DOE is to be in a position to continue removal and vitrification of the high-activity sludge between now and the startup of the SWPF, including removing sludge waste from the tanks that lack full secondary containment, and to operate the SWPF efficiently after its construction is complete, DOE must proceed with Interim Salt Processing. The only practical way DOE will be able to move forward with sludge vitrification without significant disruption and delay, and assure efficient operation of the SWPF, is to use interim salt processing technologies to remove and dispose of a limited amount of the salt waste currently in the tanks during this interim period. Otherwise, DOE would be forced to decrease, postpone, and eventually halt the on-going activities to remove and stabilize tank waste that currently are reducing risk to the occupational workers, the public, and the environment.

IV. Supplement Analysis

To determine whether the proposed action warrants a supplement to the SPA SEIS or a new EIS, DOE prepared the SA, Salt Processing Alternatives at the Savannah River Site (DOE/EIS–0082–S2–SA–01). In the SA DOE compared the impacts of implementing Interim Salt Processing followed by High Capacity Salt Processing to the impacts of the salt processing alternatives evaluated in the SPA SEIS.

Using the DDA process from 2006 until about 2011, salt waste with a Cs concentration of about 0.2 Ci/gal and an actinide concentration of about 41 nCi/g, totaling about 2.5 MCi, will be sent to the Saltstone Production Facility and then to the Saltstone Disposal Facility.

Salt waste processed through the ARP and MCU, which will operate from 2007 until the SWPF becomes operational will have a Cs concentration of about 0.1 Ci/gal and an actinide concentration comparable to SWPF waste (*i.e.*, less than 10 nCi/g) after processing, and will result in about 0.3 MCi processed through the Saltstone Production Facility for disposal at the Saltstone Disposal Facility. These concentrations are the same as those described in the SPA SEIS for salt waste processed using the CSSX technology.

After the SWPF becomes operational in 2011, waste sent to the Saltstone Disposal Facility will have concentrations the same as those evaluated in the SPA SEIS, until waste processing is completed. In all, implementing Interim Salt Processing followed High Capacity Salt Processing using the CSSX technology at the SWPF will result in disposal of about 3.0 MCi, or 1.3 percent of the total curies contained in the salt waste, at the Saltstone Disposal Facility.[4]

The SA addressed the impacts of the processing and disposal of higher concentrations of actinides during Interim Salt Processing than evaluated in the Salt Processing Alternatives SEIS. These higher concentrations will be found in that fraction of the salt waste segregated using the DDA process and sent directly for disposal without treatment in the ARP and MCU.

For the analysis presented in the SA, DOE conservatively assumed the entire salt waste inventory, processed through the SWPF using the CSSX for the operating life of the facility, would be sent to the Saltstone Production Facility with an actinide concentration of 100 nCi/g, the concentration limit for Class C waste. However, when Interim Salt Processing is implemented, concentrations will be less. That is, about 41 nCi/g resulting from the DDA process will be sent to the Saltstone Production Facility without treatment in ARP and MCU from 2006 until about 2011 when the SWPF becomes operational. DOE estimates that only about 6.8 Mgal or about 6 percent of the total salt waste inventory will have an average concentration of about 41 nCi/g. For the SA analysis DOE used the same Cs concentration DOE used for the SPA SEIS. The differences in impacts

[4] Due to uncertainties in the characterization of the salt waste, the total curies disposed could range up to 5.0 MCi. The uncertainty concerning disposal of 3.0 MCi or up to about 5.0 MCi is inconsequential in light of the Direct Disposal in Grout impacts analysis found in the SPA SEIS. As explained in the SPA SEIS, the impacts of the Direct Disposal in Grout alternative are greater than those of the other alternatives. DOE concluded, however, that any of the alternatives evaluated, including Direct Disposal in Grout, could be implemented with only small and acceptable environmental impacts.

are therefore attributed solely to the increased actinide concentration.

Short-Term Impacts

As evaluated in the SPA SEIS, short-term impacts are incurred during operation of the salt waste processing facilities, and long-term impacts are those resulting from release of disposed radionuclides from the Saltstone Disposal Facility. As described in the SA, differences in short-term impacts resulting from implementing Interim Salt Processing followed by SWPF operation using the CSSX technology will be small compared to operation of the CSSX technology as described in the SPA SEIS. Modifications to the Saltstone Production Facility were completed within the existing structure and result in no new land disturbance. Impacts from construction of the MCU will not differ from those described for the pilot plant in the SPA SEIS. The existing 512–S and 241–96H facilities will be modified for the ARP and will be operated remotely. No adverse impacts are anticipated from construction. Implementation of Interim Salt Processing will not necessitate changes in the design or operation of the SWPF.

There is the potential for short-term impacts to the health of workers and the public due to radiation doses from airborne releases of Cs and actinides from processing activities. For example, the dose to the maximum exposed individual would increase from the 0.31 millirem analyzed under the Caustic Side Solvent Extraction alternative in the SPA SEIS to 0.58 millirem (due to increased actinide concentrations in that portion of the salt waste segregated using DDA but not treated using ARP and MCU before disposal). Similar small increases would occur in involved worker doses and non-involved worker doses. The 0.31 millirem dose to the maximum exposed individual would result in a probability of a latent cancer fatality of about 2 chances in 1,000,000 (2.0×10^{-6}). The 0.58 millirem dose to the maximum exposed individual would result in a probability of a latent cancer fatality of about 3.7 chances in 1,000,000 (3.7×10^{-6}).

Long-Term Impacts

In the SA, DOE compares calculated doses and impacts from the SPA SEIS (the SWPF using the CSSX technology) and the increased actinide concentrations in the Saltstone Disposal Facility from implementing Interim Salt Processing followed by SWPF operation. Three scenarios are used. In the Agricultural Scenario an individual is assumed to unknowingly farm and constructs and lives in a permanent residence on the vaults. At 100 years post-closure a sufficient layer of soil would be present over the still-intact disposal vaults so that the resident would be unaware that the residence was constructed over the vaults. At 1,000 years post-closure the saltstone is assumed to have weathered sufficiently so that the resident could construct a residence without being aware of the presence of the saltstone.

Under the Agricultural Scenario the doses and latent cancer fatalities resulting from Interim Salt Processing followed by SWPF operation using the CSSX technology increase slightly. Under the Residential Scenario at 100 Years, impacts from Interim Salt Processing would be comparable to Caustic Side Solvent Extraction analyzed in the SPA SEIS. For the Residential Scenario at 100 Years doses are dominated by Cs, which has largely decayed by 1,000 years post-closure.

When Interim Salt Processing followed by SWPF operation using the CSSX technology is implemented, waste with a concentration of about 41 nCi/g resulting from the DDA process without ARP and MCU treatment will be sent to the Saltstone Disposal Facility until SWPF becomes operational. Using ARP and throughout the operating life of the SWPF, salt waste sent to the Saltstone Disposal Facility will have actinide concentrations of 10 nCi/g or less. Long-term impacts will be less than shown in the SA when DOE implements Interim Salt Processing followed by SWPF because the actual inventory of actinides disposed of in the Saltstone Disposal Facility will be less than assumed in the calculation.

V. Conclusions

DOE will process about 98.7 percent of the salt waste inventory (about 220 of about 223 MCi) using the CSSX technology as described in the SPA SEIS. When SWPF becomes operational the CSSX technology will be used to process the inventory of salt waste that was not processed during interim salt processing. Interim Salt Processing followed by High Capacity Salt Processing through SWPF using the CSSX technology does not constitute a substantial change in actions previously analyzed and does not present significant new circumstances or information relevant to environmental concerns and bearing on the impacts of DOE's salt processing and waste disposal program. Therefore, DOE does not need to undertake additional NEPA analysis, and DOE will implement Interim Salt Processing followed by High Capacity Salt Processing through SWPF using the CSSX technology to relieve tank space limitations and assure that vitrification of the high-activity fraction of liquid radioactive waste (sludge waste) at the Savannah River Site will continue uninterrupted while construction of the SWPF is completed.

Issued in Washington, DC, this 17th day of January 2006.

James A. Rispoli,

Assistant Secretary for Environmental Management.

[FR Doc. E6–818 Filed 1–23–06; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Section 3116 Determination for Salt Waste Disposal at the Savannah River Site

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of Availability.

SUMMARY: The Department of Energy (DOE) announces the availability of a section 3116 determination for the disposal of separated, solidified, low-activity salt waste at the Savannah River Site (SRS) near Aiken, South Carolina. Section 3116 of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005 authorizes the Secretary of Energy, in consultation with the Nuclear Regulatory Commission, to determine that certain waste from reprocessing is not high-level waste (HLW) if it meets the statutory criteria set forth in Section 3116. The Section 3116 determination sets forth the basis on which the Secretary has determined that the salt waste is not high-level waste because it (1) does not require permanent isolation in a deep geologic repository, (2) has had highly radioactive radionuclides removed to the maximum extent practical, and (3) meets the NRC performance objectives for the disposal of low level waste. In a separate notice published in today's **Federal Register**, DOE is also making available the amended Record of Decision for Savannah River Site Salt Processing Alternatives Final Supplemental Environmental Impact Statement, originally issued on October 17, 2001 (66 FR 52752).

ADDRESSES: The final determination, as well as DOE's responses to the public comments received on the draft determination, are available on the Internet at *http://apps.em.doe.gov/swd,* and are publicly available for review at the following locations: U.S. Department of Energy, Public Reading Room, 1000 Independence Avenue,

SW., Room 1E–190, Washington, DC 20585, Phone: (202) 586–5955, or Fax: (202) 586–0575; and U.S. Department of Energy, Savannah River Operations Office, Public Reading Room, 171 University Parkway, Aiken, SC 29801, Phone: (803) 641–3320, or Fax: (803) 641–3302.

SUPPLEMENTARY INFORMATION: As of November 2005 there are 36.4 million gallons (Mgal) of liquid radioactive waste stored in underground waste storage tanks at SRS. The waste consists of two distinct kinds of material: approximately 2.6 Mgal of sludge, comprised primarily of metals that settled at the bottom of the tanks; and approximately 33.8 Mgal of salt waste, which is comprised of concentrated salt solution (supernate) and crystallized saltcake.

DOE's plans call for stabilizing and disposing of retrieved sludge in a deep geologic repository for spent nuclear fuel and high-level radioactive waste. This will be done by stabilizing the HLW in a borosilicate glass matrix through vitrification in a facility known as the Defense Waste Processing Facility (DWPF). This process has been ongoing since 1996.

Regarding the salt waste, DOE plans to remove cesium, strontium, and actinides from these materials using a variety of technologies, combining the removed cesium, strontium, and actinides with the sludge being vitrified in DWPF, and solidifying the remaining low-activity salt stream into a grout matrix, known as saltstone grout, suitable for disposal in vaults at the Saltstone Disposal Facility at SRS. The disposal of this low-activity salt stream on site is the subject of this section 3116 determination.

DOE is separating the salt waste to segregate the low-activity fraction using a two-phase, three-part process. The first phase will involve two parts to treat the lower activity salt waste: (1) Beginning in 2006, DOE will process a minimal amount of the lowest-activity salt waste through a process involving deliquification, dissolution, and adjustment of the waste; and (2) beginning in 2007, DOE will process a minimal amount of additional salt waste with slightly higher activity levels using an Actinide Removal Process and a Modular Caustic Side Solvent Extraction Unit. The second, and longer-term phase, which is scheduled to begin in 2011, involves the separation and processing of the remaining (and by far the majority) of the salt waste using a high capacity Salt Waste Processing Facility, augmented as necessary by the Actinide Removal Process. This second phase will begin as soon as the Salt Waste Processing Facility is constructed, permitted by the State of South Carolina, and operational.

DOE believes that this two-phase, three-part approach to processing and disposing of the salt waste at SRS will enable it to complete cleanup and closure of the tanks years earlier and maximize reduction of the potential risks that the tank wastes pose to the environment, the public, and SRS workers. Taken together, the various technologies that will be used are expected to result in the removal and vitrification through the DWPF of 98 to 99 percent of the total radioactivity currently contained in the salt waste, while minimizing the time that waste will be stored in the underground tanks, some of which have a known history of leaks.

Issued in Washington, DC, on January 17, 2006.

James A. Rispoli,

Assistant Secretary for Environmental Management.

[FR Doc. E6–814 Filed 1–23–06; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL06–46–000]

Tucson Electric Power Company, Complainant, v. El Paso Electric Company, Respondent; Notice of Complaint

January 17, 2006.

Take notice that on January 11, 2006, Tucson Electric Power Company (TEP) filed a complaint against El Paso Electric Company (EPE) pursuant to Rule 206 of the Commission's Rules. TEP states that EPE has refused to permit TEP to use transmission rights on certain EPE transmission facilities that were assigned to it in a Tucson-El Paso Power Exchange and Transmission Agreement on file with the Commission (Power Exchange Agreement) for transmission of electricity from the newly-constructed Luna Generating Station near Deming, NM, to the TEP electric system. TEP has asked for Fast Track Processing of the Complaint and for prompt issuance of an order requiring EPE to refrain from disconnecting the Luna Generating Station to the TEP grid and to transmit electricity from TEP's share of the Luna Generating Station to the TEP service territory in accordance with the terms of the Power Exchange Agreement.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on January 31, 2006.

Magalie R. Salas,

Secretary.

[FR Doc. E6–792 Filed 1–23–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

January 17, 2006.

Take notice that the Commission received the following electric rate filings.

Docket Numbers: ER01–205–010; ER98–2640–008; ER98–4590–006; ER99–1610–013; EL05–115–000.

Applicants: Xcel Energy Services, Inc.; Northern States Power Company; Public Service Company of Colorado; Southwestern Public Service Company,

New Century Services, Inc.; Xcel Energy Services, Inc.

Description: Xcel Energy Services, Inc., on behalf of Southwestern Public Service Co. *et al.* submit an amendment to its updated market power analysis in response to FERC's December 8, 2005 letter and January 12, 2006 revision filing for Attachment B to this filing.

Filed Date: January 10, 2006.

Accession Number: 20060112–0038.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER01–642–004; ER01–1335–006; ER01–1011–008.

Applicants: CottonWood Energy Company LP; Magnolia Energy LP; Redbud Energy LP.

Description: Cottonwood Energy, LP, Magnolia Energy LP and Redbud Energy LP submit an amended notification of change in status under market-based rate authority.

Filed Date: January 10, 2006.

Accession Number: 20060112–0035.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER01–642–005; ER01–1335–007; ER01–1011–009.

Applicants: CottonWood Energy Company LP; Magnolia Energy LP; Redbud Energy LP.

Description: Cottonwood Energy Co., LP *et al.* submit revisions to their respective market-based tariff to include a Conduct of Conduct.

Filed Date: January 10, 2006.

Accession Number: 20060113–0145.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER03–394–004; ER03–427–004; ER03–175–006.

Applicants: Elk Hills Power, LLC; Mesquite Power, LLC, Termoelectrica U.S., LLC.

Description: Elk Hills Power, LLC, Mesquite Power, LLC, *et al.* submit an updated market power analysis pursuant to FERC's March 21, 2003 Order.

Filed Date: January 10, 2006.

Accession Number: 20060113–0124.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER05–1312–001; EC05–123–000.

Applicants: Monongahela Power Company and Columbus Southern Power Company.

Description: Monongahela Power Co., on behalf of Columbus Southern Power Co., notifies FERC that the dispositions and acquisition of the jurisdiction facilities authorized by such order was consummated on December 31, 2005.

Filed Date: January 10, 2006.

Accession Number: 20060113–0146.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER06–318–001.

Applicants: North American Energy Credit and Clearing.

Description: North American Energy Credit and Clearing submits supplemental information and a revised rate schedule to amend the Petition for Acceptance of Initial Rate Schedule, Wavier and Blanket Authority.

Filed Date: January 10, 2006.

Accession Number: 20060113–0147.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER06–326–001.

Applicants: North American Energy Credit and Clearing.

Description: North American Energy Credit & Clearing submits supplemental information and a revised rate schedule to amend the Petition for Acceptance of Initial Rate Schedule, Waivers & BlanketAuthority.

Filed Date: January 10, 2006.

Accession Number: 20060113–0148.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER06–463–000.

Applicants: Alcoa Power Generating, Inc.

Description: Alcoa Power Generating, Inc., submits the required ministerial changes to the Large Generator Interconnection Agreement, Small Generator Interconnection Procedures and Small Gen. Interconnection Agreement sections of its Yadkin OATT.

Filed Date: January 10, 2006.

Accession Number: 20060112–0323.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER06–464–000.

Applicants: Highlands Energy Group LLC.

Description: Highlands Energy Group, LLC's petition for acceptance of initial rate schedule, waivers, and blanket authority.

Filed Date: January 10, 2006.

Accession Number: 20060112–0324.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER06–466–000.

Applicants: EL Paso Electric Company.

Description: El Paso Electric Co., submits an unexecuted Service Agreement with Tucson Electric Power Co.

Filed Date: January 10, 2006.

Accession Number: 20060112–0326.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER06–470–000.

Applicants: Alcoa Power Generating Inc.

Description: Alcoa Power Generating Inc., submits required ministerial changes to the Large Generator Interconnection Agreement, and Small Generator Interconnection Agreement sections of its Tapoco Division OATT.

Filed Date: January 10, 2006.

Accession Number: 20060112–0329.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER96–1551–015; ER01–615–011.

Applicants: Public Service Company of New Mexico.

Description: Public Service Co. of New Mexico, submits filing of a possible change in status with regard to the characteristics that the Commission previously relied upon in granting PNM Market-Based Rate Authority.

Filed Date: January 10, 2006.

Accession Number: 20060113–0177.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER98–1150–007.

Applicants: Tucson Electric Power Company.

Description: Tucson Electric Power Co., submits filing of a change in status with regard to the characteristics that the Commission relied upon in granting market-based rate authority.

Filed Date: January 10, 2006.

Accession Number: 20060113–0125.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER99–1757–009; EL05–67–000.

Applicants: The Empire District Electric Company.

Description: The Empire District Electric Co., submits additional information in response to the Commission's deficiency letter order dated December 9, 2005.

Filed Date: January 9, 2006.

Accession Number: 20060112–0306.

Comment Date: 5 p.m. Eastern Time on Monday, January 30, 2006.

Docket Numbers: ER99–3077–002.

Applicants: Colorado Power Partners.

Description: Colorado Power Partners submits an amendment to its triennial updated market power analysis and substitute tariff sheets to FERC Electric Tariff, Original Volume No. 1.

Filed Date: January 10, 2006.

Accession Number: 20060112–0036.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Docket Numbers: ER99–3197–002.

Applicants: BIV Generation Company LLC.

Description: BIV Generation Co., LLC submits an amendment to its triennial updated market power analysis and Substitute tariff sheets to FERC Electric Tariff, Original Volume No. 1.

Filed Date: January 10, 2006.

Accession Number: 20060112–0037.

Comment Date: 5 p.m. Eastern Time on Tuesday, January 31, 2006.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern Time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. 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. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E6–789 Filed 1–23–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11588–011, Alaska]

Alaska Power and Telephone Company; Notice of Availability of Environment Assessment

January 17, 2006.

An environmental assessment (EA) is available for public review. The EA was prepared for an application filed by the Alaska Power and Telephone Company (licensee) on October 17, 2005, requesting Commission approval to make certain design and site location changes to project facilities as licensed. The changes include: (1) Constructing a 675-foot-long, 9 foot horseshoe tunnel to provide a route for the upper section of the penstock and access to the diversion structure, (2) altering the penstock composition and alignment and the alignment and width of the access road for a length of 2,860 feet, (3) moving the powerhouse 80 feet south of the original location and increase the tailrace length from 75 feet to 163 fee, (4) moving the marine access about 600 feet north of the original location and construct a 250-foot-long jetty with a quay and boat ramp; and (5) constructing a 33,000 square-foot rockfill staging area onshore.

The EA evaluates the environmental impacts that would result from approving the licensee's proposed changes to certain project facilities and locations. Some additional ground disturbance would occur but impacts to the terrestrial and marine environments are expected to be minor and short term. The EA finds that approval of the amendment application would not constitute a major Federal action significantly affecting the quality of the human environment.

A copy of the EA is attached to a Commission order titled ''Order Amending License'', issued January 12, 2006, and is available in the Commission's Public Reference Room. A copy of the EA may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number (P–11588) in the docket field to access the document. For assistance, call (202) 502–8222 or (202) 502–8659 (for TTY).

Magalie R. Salas,

Secretary.

[FR Doc. E6–791 Filed 1–23–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Non-Project Use of Project Lands and Waters and Soliciting Comments, Motions To Intervene, and Protests

January 17, 2006.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-Project Use of Project Lands and Waters.

b. *Project No.:* 2503–092.

c. *Date Filed:* December 21, 2005.

d. *Applicant:* Duke Power, a division of Duke Energy Corporation.

e. *Name of Project:* Keowee-Toxaway Project.

f. *Location:* Lake Keowee is located in Pickens and Oconee County, South Carolina. This project does not occupy any tribal or federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r) and 799 and 801.

h. *Applicant Contact:* Mr. Joe Hall, Lake Management Representative; Duke Energy Corporation; P.O. Box 1006; Charlotte, NC 28201–1006; 704–382–8576.

i. *FERC Contact:* Any questions on this notice should be addressed to Brian Romanek at (202) 502–6175 or by e-mail: *Brian.Romanek@ferc.gov.*

j. *Deadline for filing comments and or motions:* February 17, 2006.

All documents (original and eight copies) should be filed with: Ms. Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426. Please include the project number (P–2503–092) on any comments or motions filed. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages e-filings.

k. *Description of Request:* Duke Power, licensee for the Keowee-Toxaway Hydroelectric Project, has requested Commission authorization to lease project lands to Outerbanks, Inc. for the purpose of reconfiguring a marina previously approved by the Commission. The reconfiguration would reduce the existing marina footprint from 1.62 acres to 1.56 acres and the number of boat slips from 56 to 54. The marina would accommodate residents of the Outerbanks Subdivision on Lake

Keowee off of Hatteras Ridge Road in Six Mile, South Carolina. (Pickens County).

l. *Location of the Application:* This filing is available for review at the Commission or may be viewed on the Commission's Web site at *http://www.ferc.gov,* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. Agency Comments—Federal, state, and local agencies are invited to file comments on the described applications. A copy of the applications may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. E6–790 Filed 1–23–06; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8024–4]

Office of the Science Advisor; Office of Research and Development; Broad Agency Announcement for Conferences, Workshops, or Meetings

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is issuing this Broad Agency Announcement (BAA) soliciting applications from eligible applicants for the planning, arranging, administering, and conducting of conferences, workshops, and/or meetings in the areas of EPA mission related issues connected to protecting, human health and safeguarding the natural environment; advancing the scientific and technical research that promotes environmental protection; exploring current and emerging issues of importance to environmental protection; and/or encouraging collaboration among the nation's best scientists and engineers in academia, business and nonprofit research institutes.

DATES: The opening date for this BAA is January 19, 2006 and it will close on January 18, 2007. The Agency will make funding decisions on a quarterly basis beginning approximately April 18, 2006, and thereafter approximately every three months. The next funding decisions will be approximately on July 17, 2006, October 16, 2006, and January 16, 2007. However, in order for a proposal to be considered for funding, it must be received by EPA no later than three months prior to the start of the conference for which the applicant is requesting EPA funding under this BAA and no later than January 18, 2007.

FOR FURTHER INFORMATION CONTACT: Eligibility Contact: Michael Bender, 202–564–6829; email: *bender.michael@epa.gov* Electronic Submissions: ORD Call Center (Phone: 202–343–5500) Technical Contact: [*Michael Bender, Project Officer*]; Phone: 202–564–6829; e-mail: *bender.michael@epa.gov*

SUPPLEMENTARY INFORMATION:

I. Introduction

Advancing sound science on cross-cutting issues at EPA is a goal of the Office of the Science Advisor (OSA), Office of Research and Development (ORD) which is based at EPA headquarters in Washington, DC. OSA, Office of Research and Development's mission includes supporting leading-edge research to stimulate the sound use of science and technology to fulfill EPA's mission to protect human health and safeguard the natural environment. One way to accomplish this is to provide broad informational technical support through conferences, which further environmental research by communicating ideas, knowledge, expertise, innovation and creativity in solving complex environmental issues. The Agency intends to assist in this sharing of information with the broad scientific community by awarding grant/cooperative agreement support for such efforts. The Agency also encourages the coordination and use of EPA funding with other Federal and/or non Federal sources of funds to leverage additional resources to carry out the proposed effort. Applicants may use their own funds or other resources (*e.g.* support from a collaborating institution or organization) for a voluntary match or cost share if the standards at 40 CFR 30.23 or 40 CFR 31.24, as applicable, are met.

II. Eligibility Information

States, territories and possessions, and Tribal nations of the U.S., including the District of Columbia, public and private universities and colleges, hospitals, laboratories, local governments, other public or private nonprofit institutions, are eligible to apply. Universities and educational institutions must be subject to OMB Circular A–21. Profit-making firms are not eligible to receive grants from the EPA under this program.

Eligible nonprofit organizations include any organizations that meet the definition of nonprofit in OMB Circular A–122. However, nonprofit organizations described in Section 501(c)(4) of the Internal Revenue Code that lobby are not eligible to apply.

III. Award Information

Anticipated Type of Award: Grant or Cooperative Agreement.

Estimated Number of Awards Under this BAA: Approximately 25 awards depending upon the amount of any individual award.

Anticipated Funding Amount: Office of the Science Advisor (OSA), Office of Research and Development may have up to an estimated $150,000 for awards under this BAA; other ORD offices may have additional funding of up to an estimated $600,000 available for awards under this BAA—therefore the total estimated amount available for all awards under this BAA may be approximately $750,000.

IV. Potential Funding per Grant

EPA may award funding under this BAA in the following two categories:

1. Meeting and workshop support up to $25,000 per agreement including direct and indirect costs. This category is for major support of small scale, focused meetings and workshops on a specific subject or subjects, or for partial support of a larger conference.

2. Large conference support up to $75,000 per agreement including direct and indirect costs. This category is for major support of broader conferences that include a wide range of subjects relating to environmental research.

EPA will not consider applications for less than $5,000.

All grants and cooperative agreements will have a duration of up to 1 year to provide for follow-up activities such as publication of reports and proceedings. Cost-sharing is not required for awards under this BAA.

V. Award Notices

EPA will notify successful and unsuccessful applicants by e-mail. Applicants selected for funding will be required to provide additional information listed under ''Award Notices.'' EPA may require selected applicants to submit additional forms and certifications. The application will then be forwarded to EPA's Grants Administration Division for award in accordance with the EPA's procedures. The Agency is not obligated to fund selected applicants until a grant is awarded by EPA's Grants Administration Division.

Applicants are cautioned that only a grants officer can bind the Government to the expenditure of funds; preliminary selection by EPA does not guarantee an award will be made. The official notification of an award will be made by the Agency's Grants Administration Division.

Nonprofit applicants recommended for funding under this BAA will be subject to a preaward administrative capability review consistent with sections 8.b, 8.c, and 9.d of EPA Order 5700.8, *EPA Policy on Assessing Capabilities of Non-Profit Applicants for Managing Assistance Awards* (*http://www.epa.gov/ogd/grants/regulations.htm*).

Before or after an award, applicants may be required to provide additional quality assurance documentation.

Further information, if needed, may be obtained from the EPA officials indicated under the section titled: ''For Further Information Contact.'' Information regarding this BAA obtained from sources other than these Agency Contacts may not be accurate. E-mail inquiries are preferred. To view the full Broad Agency Announcement go to: *http://www.epa.gov/ord/htm/grantopportunity.htm*.

Dated: January 18, 2006.

William H. Farland,

Chief Scientist, Office of the Science Advisor.

[FR Doc. E6–810 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8023–9]

Clean Water Act Section 303(d): Final Agency Action on 44 Total Maximum Daily Loads (TMDLs)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the final agency action on 44 TMDLs prepared by EPA Region 6 for waters listed in the state of Arkansas, under section 303(d) of the Clean Water Act (CWA). These TMDLs were completed in response to the lawsuit styled *Sierra Club, et al.* v. *Clifford, et al.*, No. LR–C–99–114. Documents from the administrative record files for the final 44 TMDLs, including TMDL calculations and responses to comments, may be viewed at *http://www.epa.gov/earth1r6/6wq/artmdl.htm.*

ADDRESSES: The administrative record files for these 44 TMDLs may be obtained by writing or calling Ms. Diane Smith, Environmental Protection Specialist, Water Quality Protection Division, U.S. Environmental Protection Agency Region 6, 1445 Ross Ave., Dallas, TX 75202–2733. Please contact Ms. Smith to schedule an inspection.

FOR FURTHER INFORMATION CONTACT: Diane Smith at (214) 665–2145.

SUPPLEMENTARY INFORMATION: In 1999, five Arkansas environmental groups, the Sierra Club, Federation of Fly Fishers, Crooked Creek Coalition, Arkansas Fly Fishers, and Save our Streams (plaintiffs), filed a lawsuit in Federal Court against the EPA, styled *Sierra Club, et al.* v. *Clifford, et al.*, No. LR–C–99–114. Among other claims, plaintiffs alleged that EPA failed to establish Arkansas TMDLs in a timely manner.

EPA Takes Final Agency Action on 44 TMDLs

By this notice EPA is taking final agency action on the following 44 TMDLs for waters located within the state of Arkansas:

Segment-Reach	Waterbody name	Pollutant
08020401–003	Wabbaseka Bayou	Siltation/turbidity.
11110205–011	Cadron Creek	Siltation/turbidity..
11110205–012	Cadron Creek	Siltation/turbidity.
11110203–927	White Oak Creek	Siltation/turbidity.
08020302–004	Bayou Deview	Siltation/turbidity.
08020302–005	Bayou Deview	Siltation/turbidity.
08020302–006	Bayou Deview	Siltation/turbidity.
08020302–007	Bayou Deview	Siltation/turbidity.
08020302–009	Bayou Deview	Siltation/turbidity.
08020302–016	Cache River	Siltation/turbidity.
08020302–017	Cache River	Siltation/turbidity.
08020302–018	Cache River	Siltation/turbidity.
08020302–019	Cache River	Siltation/turbidity.
08020302–020	Cache River	Siltation/turbidity.
08020302–021	Cache River	Siltation/turbidity.
08020302–027	Cache River	Siltation/turbidity.
08020302–028	Cache River	Siltation/turbidity.
08020302–029	Cache River	Siltation/turbidity.
08020302–031	Cache River	Siltation/turbidity.
08020302–032	Cache River	Siltation/turbidity.
11010013–006	Village Creek	Siltation/turbidity.
11010013–007	Village Creek	Siltation/turbidity.

Segment-Reach	Waterbody name	Pollutant
11010013–008	Village Creek	Siltation/turbidity.
11010013–012	Village Creek	Siltation/turbidity.
11010013–014	Village Creek	Siltation/turbidity.
11010014–009	Ten Mile Creek	Siltation/turbidity.
11010012–004	Strawberry River	Siltation/turbidity.
11010012–005	Strawberry River	Siltation/turbidity.
11010012–006	Strawberry River	Siltation/turbidity.
110100 12–008	Strawberry River	Siltation/turbidity.
11010012–009	Strawberry River	Siltation/turbidity.
11010012–010	Little Strawberry River	Siltation/turbidity.
11010012–011	Strawberry River	Siltation/turbidity.
11010001–023	West Fork White River	Siltation/turbidity.
11010001–024	White River	Siltation/turbidity.
08020203–012	Tyronza River	Siltation/turbidity.
11110105–001	Poteau River near Fort Smith	Siltation/turbidity.
11110105–031L	Poteau River near Waldron	Total phosphorus, Copper, and Zinc.
11140302–003	Days Creek	Nitrate.
11140109–919	Rolling Fork	Total phosphorus, and Nitrate.
11010001–045L	Osage Creek near Berryville	Total phosphorus.

EPA requested the public to provide EPA with any significant data or information that might impact the 44 TMDLs at **Federal Register** Notices: Volume 70, Number 217, pages 68448–68449 (November 10, 2005) and Volume 70, Number 46, page 11971 (March 10, 2005). The comments received and EPA's response to comments may be found at *http://www.epa.gov/earth1r6/6wq/artmdl.htm.*

Dated: January 10, 2006.

Miguel I. Flores,

Director, Water Quality Protection Division, Region 6.

[FR Doc. E6–813 Filed 1–23–06; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

[Docket No. 06–01]

Worldwide Relocations, Inc., All-in-One Shipping, Inc., Boston Logistics Corp., Around the World Shipping, Inc., Tradewind Consulting, Inc., Global Direct Shipping, Megan K. Karpick (a.k.a. Catherine Kaiser, Kathryn Kaiser, Catherine Kerpick, Megan Kaiser and Alexandria Hudson), Martin J. McKenzie, Patrick John Costadoni, Elizabeth F. Hudson, Sharon Fachler, and Oren Fachler, et al.—Possible Violations of Sections 8, 10 and 19 of the Shipping Act of 1984 and the Commission's Regulations at 46 CFR 515.3, 515.21 and 520.3; Notice of Order of Investigation and Hearing

Notice is given that on January 11, 2006 the Federal Maritime Commission issued an Order of Investigation and Hearing to determine whether nine apparently related household goods moving companies and their owners and/or primary corporate officers were operating unlawfully. Named in the order are: Moving Services, L.L.C.; Worldwide Relocations, Inc.; International Shipping Solutions, Inc.; Dolphin International Shipping, Inc.; All-in-One Shipping, Inc.; Boston Logistics Corp.; Around the World Shipping, Inc.; Tradewind Consulting, Inc.; Global Direct Shipping; Sharon Fachler; Oren Fachler; Lucy Norry; Patrick J. Costadoni; Steve Kuller; Megan K. Karpick (a.k.a. Catherine Kaiser, Kathryn Kaiser, Catherine Kerpick, Megan Kaiser and Alexandria Hudson); Barbara Deane (a.k.a. Barbara Fajardo); Baruch Karpick; Martin J. McKenzie; Joshua S. Morales; Elizabeth F. Hudson; Daniel E. Cuadrado (a.k.a. Daniel Edward); Ronald Eaden; and Robert Bachs (collectively ''the Respondents'').

The Commission has received over 250 consumer complaints from shippers regarding the above individuals and companies alleging, among other things, that the companies: failed to deliver the cargo and refused to return pre-paid ocean freight; lost the cargo; charged the shipper for marine insurance which they never obtained; misled the shipper as to the whereabouts of cargo; charged the shipper an inflated rate and withheld cargo until that rate was paid; and failed to pay the common carrier. In many cases, the shipper was forced to pay another carrier or warehouse a second time in order to have the cargo released. In addition, none of the companies or individuals listed is licensed as OTIs by the Federal Maritime Commission, nor have they provided proof of financial responsibility, or published a tariff showing their rates.

This proceeding seeks to determine: (1) Whether Respondents violated sections 8, 10, and 19 of the Shipping Act of 1984 and the Commission's regulations at 46 CFR Parts 515 and 520 by operating as non-vessel-operating common carriers in the U.S. trades without obtaining licenses from the Commission, without providing proof of financial responsibility, without publishing an electronic tariff, and by failing to establish, observe, and enforce just and reasonable regulations and practices relating to or connected with receiving, handling, storing, or delivering property; (2) Whether, in the event one or more violations of sections 8, 10 and 19 of the Shipping Act of 1984 and 46 CFR Parts 515 and 520 are found, civil penalties should be assessed and, if so, the identity of the persons and/or corporations to whom the penalties should be assessed and the amount of the penalties to be assessed; (3) Whether, in the event violations are found, appropriate cease and desist orders should be issued.

The full text of this order may be viewed on the Commission's home page at *http://www.fmc.gov* or at the Office of the Secretary, Room 1046, 800 North Capitol Street, NW., Washington DC. Any person may file a petition for leave to intervene in accordance with 46 CFR 502.72.

Bryant L. VanBrakle,

Secretary.

[FR Doc. E6–786 Filed 1–23–06; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System

SUMMARY: Background.

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act, as per 5 CFR 1320.16, to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board under conditions set forth in 5 CFR 1320 Appendix A.1. Board–approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the OMB 83-Is and supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Request for comment on information collection proposals

The following information collections, which are being handled under this delegated authority, have received initial Board approval and are hereby published for comment. At the end of the comment period, the proposed information collections, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected; and

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments must be submitted on or before March 27, 2006.

ADDRESSES: You may submit comments, identified by FR 2502q, FR Y–8, FR 2886b, FR 2050, or FR 2415 by any of the following methods:

Agency Web Site: *http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*

Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

E–mail: *regs.comments@federalreserve.gov.* Include docket number in the subject line of the message.

FAX: 202/452–3819 or 202/452–3102.

Mail: Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets, NW.) between 9 a.m. and 5 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: A copy of the proposed form and instructions, the Paperwork Reduction Act Submission (OMB 83–I), supporting statement, and other documents that will be placed into OMB's public docket files once approved may be requested from the agency clearance officer, whose name appears below.

Michelle Long, Federal Reserve Board Clearance Officer (202/452–3829), Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may contact (202/263–4869), Board of Governors of the Federal Reserve System, Washington, DC 20551.

Proposal to approve under OMB delegated authority the extension for three years, with revision, of the following reports:

1. Report title: Quarterly Report of Assets and Liabilities of Large Foreign Offices of U.S. Banks

Agency form number: FR 2502q

OMB control number: 7100–0079

Frequency: Quarterly

Reporters: Large foreign branches and banking subsidiaries of U.S. depository institutions

Annual reporting hours: 826 hours

Estimated average hours per response: 3.5 hours

Number of respondents: 59

General description of report: This information collection is required (12 U.S.C. §§ 248(a) (2), 353 et seq., 461, 602, and 625) and is given confidential treatment (5 U.S.C. § 552(b) (4)).

Abstract: This reporting form collects data quarterly on the geographic distribution of the assets and liabilities of major foreign branches and subsidiaries of U.S. commercial banks and of Edge and agreement corporations. Data from this reporting form comprise a piece of the flow of funds data that are compiled by the Federal Reserve.

Current action: The Federal Reserve proposes the following revisions: (1) Discontinuing Schedule A as a result of the elimination of M3; (2) discontinuing Memorandum item 3a; (3) revising the instructions for data to be submitted for the unallocated data items; (4) reducing the reporting panel to require offices located only in the Caribbean and the United Kingdom to file the FR 2502q; and (5) conforming the names of several countries and one region to the country list compiled by the U.S. Treasury.

2. Report title: Consolidated Report of Condition and Income for Edge and Agreement Corporations

Agency form number: FR 2886b

OMB control number: 7100–0086

Frequency: Quarterly

Reporters: Edge and agreement corporations

Annual reporting hours: 3,055

Estimated average hours per response: 14.7 banking corporations, 8.5 investment corporations

Number of respondents: 19 banking corporations, 57 investment corporations

General description of report: This information collection is mandatory (12 U.S.C. §§ 602 and 625). For Edge corporations engaged in banking, information collection on schedules RC–M and RC–V are held confidential pursuant to section (b)(4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)). For investment Edge corporations, only information collected on schedule RC–M are given confidential treatement pursuant to section (b)(4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Abstract: This reporting form comprises a balance sheet, income statement, two schedules reconciling changes in capital and reserve accounts, and ten supporting schedules, and it parallels the commercial bank Consolidated Reports of Condition and Income (Call Report)(FFIEC 031; OMB No. 7100–0036). The Federal Reserve uses the data collected on the FR 2886b to supervise Edge corporations, identify present and potential problems, and monitor and develop a better understanding of activities within the industry.

Current action: The Federal Reserve proposes to delete three items related to bankers acceptances, consistent with proposed changes to the Call Report and to make minor clarifications to the reporting form and instructions.

Proposal to approve under OMB delegated authority the extension for three years, without revision, of the following report:

1. Report title: Bank Holding Company Report of Insured Depository Institutions' Section 23A Transactions with Affiliates

Agency form number: FR Y–8

OMB control number: 7100–0126

Frequency: Quarterly

Reporters: All top–tier bank holding companies (BHCs), including financial holding companies (FHCs), and foreign banking organizations (FBOs) that directly own U.S. subsidiary banks.

Annual reporting hours: 53,419 hours

Estimated average hours per response: Institutions with covered transactions, 7.8 hours; institutions without covered transactions, 1 hour

Number of respondents: 6,310

General description of report: This information collection is mandatory (section 5(c)) of the Bank Holding Company Act (12 U.S.C. 1844(c)) and section 225.5(b) of Regulation Y (12 CFR 225.5(b)) and is given confidential treatment (5 U.S.C 552(b)(4) and (8)).

Abstract: This reporting form collects information on transactions between an insured depository institution and its affiliates that are subject to section 23A of the Federal Reserve Act. The primary purpose of the data is to enhance the Federal Reserve's ability to monitor bank exposures to affiliates and to ensure banks' compliance with section 23A of the Federal Reserve Act. Section 23A of the Federal Reserve Act is one of the most important statutes on limiting exposures to individual institutions and protecting against the expansion of the federal safety net.

Proposal to approve under OMB delegated authority the discontinuance of the following reports:

1. Report title: Weekly Report of Eurodollar Liabilities Held by Selected U.S. Addressees at Foreign Offices of U.S. Banks

Agency form number: FR 2050

OMB Control number: 7100–0068

Effective Date: Respondents will submit their final data for the reporting week ending March 6, 2006.

Frequency: Weekly

Reporters: Foreign branches and banking subsidiaries of U.S. depository institutions.

Annual reporting hours: 1,872 hours

Estimated average hours per response: 1.0 hour

Number of respondents: 36

General description of report: This information collection is voluntary (12 U.S.C. §§ 248(a)(2), 353 et seq., 461, 602, and 625). Individual respondent's data are confidential under section (b)(4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Abstract: The report collects data on Eurodollar deposits payable to nonbank U.S. addressees from foreign branches and subsidiaries of U.S. commercial banks and Edge and agreement corporations. The data are used for the construction of the Eurodollar component of the monetary aggregates and for analysis of banks' liability management practices.

Current Actions: The Board of Governors of the Federal Reserve System announced on November 10, 2005, that it would cease publication of the M3 monetary aggregate on March 23, 2006. M3 does not appear to contain any additional information about economic activity that is not already embodied in M2. Moreover, the role of M3 in the monetary policy process has greatly diminished over time. The costs to the Federal Reserve and the private sector of collecting data and publishing M3 now outweigh the benefits. The discontinuation of this report will reduce private sector burden by 1,872 hours per year.

2. Report title: Report of Repurchase Agreements (RPs) on U.S. Government and Federal Agency Securities with Specified Holders

Agency form number: FR 2415

OMB Control number: 7100–0074

Effective Date: Weekly reporters will submit their final FR 2415 for the report week ending March 6, 2006. Quarterly reporters will submit their final data for the week containing the last calendar day of December 2005. Since annual reporters submit data for the week containing June 30, they will no longer file the FR 2415.

Frequency: Weekly, quarterly, or annually

Reporters: U.S chartered commercial banks, U.S branches and agencies of foreign banks, thrift institutions, and credit unions

Annual reporting hours: 2,615 hours

Estimated average hours per response: 30 minutes

Number of respondents: 84 weekly, 128 quarterly, and 350 annually Small businesses are not affected.

General description of report: This information collection is voluntary (12 U.S.C. 248(a)(2) and 3105(b)) and is given confidential treatment (5 U.S.C. 552(b)(4)).

Abstract: This voluntary report collects one data item, repurchase agreements (RPs), in denominations of $100,000 or more, in immediately–available funds, on U.S. government and federal agency securities, transacted with specified holders. Depository institutions file the FR 2415 report weekly, quarterly or annually depending on the volume of their RPs. In general, the larger the respondent's level of RPs, the more frequent is its reporting. The weekly panel reports daily data once each week; the quarterly panel files daily data for the four one–week reporting periods that contain quarter–end dates; the annual panel reports daily data only for the week encompassing June 30 each year. The primary purpose of the data is for construction of the RP component of the M3 monetary aggregate and for analysis of depository institutions' funding practices.

Current Actions: The Board of Governors of the Federal Reserve System announced on November 10, 2005, that it would cease publication of the M3 monetary aggregate on March 23, 2006. M3 does not appear to contain any additional information about economic activity that is not already embodied in M2. Moreover, the role of M3 in the monetary policy process has greatly diminished over time. The costs to the Federal Reserve and the private sector of collecting data and publishing M3 now outweigh the benefits. The discontinuation of this report will reduce private sector burden by 2,615 hours per year.

Board of Governors of the Federal Reserve System, January 19, 2006.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E6–804 Filed 1–23–06; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have 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 the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors.

Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 8, 2006.

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30303:

1. David F. Barker, Kyle D. Barker, Julia K. Barker, all of Dunlap, Tennessee, and Dorris B. Birchett, Cohutta, Georgia; to acquire voting shares of Sequatchie County Bancorp, Inc., and thereby indirectly acquire voting shares of Mountain Valley Bank, both of Dunlap, Tennessee.

Board of Governors of the Federal Reserve System, January 19, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E6–807 Filed 1–23–06; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center Web site at *http://www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 17, 2006.

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30303:

1. Floridian Financial Group, Inc., Ormond Beach, Florida; to become a bank holding company by acquiring 100 percent of the voting shares of Floridian Bank, Ormond Beach, Florida (in organization).

B. Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. First National Bancorp, Inc., Kalamazoo, Michigan; to become a bank holding company by acquiring 100 percent of the voting shares of First National Bank of Michigan, Kalamazoo, Michigan.

Board of Governors of the Federal Reserve System, January 19, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E6–806 Filed 1–23–06; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 12 p.m., Monday, January 30, 2006.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Director, Office of Board Members; 202–452–2955.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: January 20, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 06–715 Filed 1–20–06; 3:13 pm]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0044]

Public Buildings Service; Information Collection; GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds

AGENCY: Public Buildings Service, GSA.

ACTION: Notice of request for comments regarding a renewal to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve a renewal of a currently approved information collection requirement regarding GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds. The clearance currently expires on May 31, 2006.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before: March 27, 2006.

FOR FURTHER INFORMATION CONTACT: Frank Giblin, Public Buildings Service, at telephone (202) 501–1856, or via e-mail to *frank.giblin@gsa.gov*.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Regulatory Secretariat (VIR), General Services Administration, Room 4035, 1800 F Street, NW., Washington, DC 20405. Please cite OMB Control No. 3090–0044, GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds, in all correspondence.

SUPPLEMENTARY INFORMATION:

A. Purpose

The general public uses GSA Form 3453, Application/Permit for Use of

Space in Public Buildings and Grounds, to request the use of public space in Federal buildings and on Federal grounds for cultural, educational, or recreational activities. A copy, sample, or description of any material or item proposed for distribution or display must also accompany this request.

B. Annual Reporting Burden

Respondents: *8,000.*
Responses Per Respondent: *1.*
Hours Per Response: *0.05.*
Total Burden Hours: *400.*
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VIR), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 208–7312. Please cite OMB Control No. 3090–0044, GSA Form 3453, Application/Permit for Use of Space in Public Buildings and Grounds, in all correspondence.

Dated: January 13, 2006.

Michael W. Carleton,

Chief Information Officer.

[FR Doc. 06–671 Filed 1–23–06; 8:45 am]

BILLING CODE 6820–23–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Annual Update of the HHS Poverty Guidelines

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice provides an update of the HHS poverty guidelines to account for last calendar year's increase in prices as measured by the Consumer Price Index.

DATES: *Effective Date:* Date of publication, unless an office administering a program using the guidelines specifies a different effective date for that particular program.

ADDRESSES: Office of the Assistant Secretary for Planning and Evaluation, Room 404E, Humphrey Building, Department of Health and Human Services (HHS), Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: For information about how the guidelines are used or how income is defined in a particular program, contact the Federal, state, or local office that is responsible for that program. Contact information for two frequently requested programs is given below:

For information about the Hill-Burton Uncompensated Services Program (free or reduced-fee health care services at certain hospitals and other facilities for persons meeting eligibility criteria involving the poverty guidelines), contact the Office of the Director, Division of Facilities Compliance and Recovery, Health Resources and Services Administration, HHS, Room 10–105, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. To speak to a person, call (301) 443–5656. To receive a Hill-Burton information package, call 1–800–638–0742 (for callers outside Maryland) or 1–800–492–0359 (for callers in Maryland). You may also visit *http://www.hrsa.gov/osp/dfcr/*. The Division of Facilities Compliance and Recovery notes that as set by 42 CFR 124.505(b), the effective date of this update of the poverty guidelines for facilities obligated under the Hill-Burton Uncompensated Services Program is sixty days from the date of this publication.

For information about the percentage multiple of the poverty guidelines to be used on immigration forms such as USCIS Form I–864, Affidavit of Support, contact U.S. Citizenship and Immigration Services at 1–800–375–5283 or visit *http://uscis.gov/graphics/howdoi/affsupp.htm*.

For information about the number of people in poverty or about the Census Bureau poverty thresholds, visit the Poverty section of the Census Bureau's Web site at *http://www.census.gov/hhes/www/poverty/poverty.html* or contact the Housing and Household Economic Statistics Information Staff at (301) 763–3242.

For general questions about the poverty guidelines themselves, contact Gordon Fisher, Office of the Assistant Secretary for Planning and Evaluation, Room 404E, Humphrey Building, Department of Health and Human Services, Washington, DC 20201—telephone: (202) 690–7507—or visit *http://aspe.hhs.gov/poverty/*.

SUPPLEMENTARY INFORMATION:

Background

Section 673(2) of the Omnibus Budget Reconciliation Act (OBRA) of 1981 (42 U.S.C. 9902(2)) requires the Secretary of the Department of Health and Human Services to update, at least annually, the poverty guidelines, which shall be used as an eligibility criterion for the Community Services Block Grant program. The poverty guidelines also are used as an eligibility criterion by a number of other Federal programs. The *poverty guidelines* issued here are a simplified version of the *poverty thresholds* that the Census Bureau uses to prepare its estimates of the number of individuals and families in poverty.

As required by law, this update is accomplished by increasing the latest published Census Bureau poverty thresholds by the relevant percentage change in the Consumer Price Index for All Urban Consumers (CPI–U). The guidelines in this 2006 notice reflect the 3.4 percent price increase between calendar years 2004 and 2005. After this inflation adjustment, the guidelines are rounded and adjusted to standardize the differences between family sizes. The same calculation procedure was used this year as in previous years. (Note that these 2006 guidelines are roughly equal to the poverty thresholds for calendar year 2005 which the Census Bureau expects to publish in final form in August 2006.)

2006 POVERTY GUIDELINES FOR THE 48 CONTIGUOUS STATES AND THE DISTRICT OF COLUMBIA

Persons in family unit	Poverty guideline
1	$9,800
2	13,200
3	16,600
4	20,000
5	23,400
6	26,800
7	30,200
8	33,600

For family units with more than 8 persons, add $3,400 for each additional person.

2006 POVERTY GUIDELINES FOR ALASKA

Persons in family unit	Poverty guideline
1	$12,250
2	16,500
3	20,750
4	25,000
5	29,250
6	33,500
7	37,750
8	42,000

For family units with more than 8 persons, add $4,250 for each additional person.

2006 POVERTY GUIDELINES FOR HAWAII

Persons in family unit	Poverty guideline
1	$11,270
2	15,180
3	19,090
4	23,000
5	26,910
6	30,820
7	34,730

2006 POVERTY GUIDELINES FOR HAWAII—Continued

Persons in family unit	Poverty guideline
8	38,640

For family units with more than 8 persons, add $3,910 for each additional person.

Separate poverty guideline figures for Alaska and Hawaii reflect Office of Economic Opportunity administrative practice beginning in the 1966–1970 period. (Note that the Census Bureau poverty thresholds—the version of the poverty measure used for statistical purposes—have never had separate figures for Alaska and Hawaii). The poverty guidelines are not defined for Puerto Rico or other outlying jurisdictions. In cases in which a Federal program using the poverty guidelines serves any of those jurisdictions, the Federal office that administers the program is responsible for deciding whether to use the contiguous-states-and-DC guidelines for those jurisdictions or to follow some other procedure.

Due to confusing legislative language dating back to 1972, the poverty guidelines have sometimes been mistakenly referred to as the ''OMB'' (Office of Management and Budget) poverty guidelines or poverty line. In fact, OMB has never issued the guidelines; the guidelines are issued each year by the Department of Health and Human Services. The poverty guidelines may be formally referenced as ''the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2).''

Some programs use a percentage multiple of the guidelines (for example, 125 percent or 185 percent of the guidelines), as noted in relevant authorizing legislation or program regulations. Non-Federal organizations that use the poverty guidelines under their own authority in non-Federally-funded activities can choose to use a percentage multiple of the guidelines such as 125 percent or 185 percent.

The poverty guidelines do not make a distinction between farm and non-farm families or between aged and non-aged units. (Only the Census Bureau poverty thresholds have separate figures for aged and non-aged one-person and two-person units).

Note that this notice does not provide definitions of such terms as ''income'' or ''family.'' This is because there is considerable variation in how different programs that use the guidelines define these terms, traceable to the different laws and regulations that govern the various programs. Therefore, questions about how a particular program applies the poverty guidelines (e.g., Is income before or after taxes? Should a particular type of income be counted? Should a particular person be counted in the family or household unit?) should be directed to the organization that administers the program.

Dated: January 18, 2006.

Michael O. Leavitt,

Secretary of Health and Human Services.

[FR Doc. 06–624 Filed 1–20–06; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Solicitation for Nominations for New Primary and Secondary Health Topics To Be Considered for Review by the United States Preventive Services Task Force

AGENCY: Agency for Healthcare Research and Quality (AHRQ), DHHS.

ACTION: Solicit for new topic nominations.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) invites individuals and organizations to nominate primary and secondary prevention topics pertaining to clinical preventive services that they would like the United States Preventive Services Task Force (USPSTF) to consider for review. A list of topics that have been recently reviewed or are currently under review by the USPSTF is listed below in the supplementary information section.

The USPSTF is an independent panel of experts that makes evidence-based recommendations regarding the provision of clinical preventive services. Clinical preventive services include screening, counseling and preventive medications. The USPSTF makes recommendations about preventive services for asymptomatic people—people without recognized signs or symptoms of the specific conditions targeted by the preventive service.

Topics can be nominated by individuals, organizations, evidence-based practice centers (EPC) and USPSTF members. The USPSTF will consider nominations and prioritize topics for review based on the following set of criteria: Public health importance (burden of suffering, potential of preventive service to reduce the burden); new evidence that has the potential to change prior recommendations including inactive ones; and, potential for greatest Task Force impact (e.g., clinical controversy, practice does not reflect evidence, inappropriate timing in delivery of services). The USPSTF will prioritize topics for which there is a performance gap and the potential to significantly improve clinical practice. Individuals and organizations may nominate new topics or topics previously reviewed by the USPSTF.

Basic Topic Nomination Requirements: Nominations must be no more than 500 words in length and must include the following information. Nominations may include an appendix that contains references and supporting documents (not included in word count).

1. Name of topic.

2. Rationale for consideration by the USPSTF, to include:

a. Primary or secondary prevention topic (screening, counseling or preventive medication).

b. Primary care relevance (aplicable clinical preventive service must be initiated in the primary care setting which can be defined as family practice, internal medicine, pediatrics or obstetrics/gynecology and provided by a primary care provider).

c. Description of public health importance (burden of disease/suffering, potential of preventive service to reduce burden, including effective interventions). Citations and supporting documents are recommended.

d. Summary of new evidence, if any, that has potential to affect the Task Force's recommendation on a previously reviewed topic. Please refer to *http://preventiveservices.ahrg.gov* for USPSTF recommendations. Citations and supporting documents are recommended.

e. Description of potential impact of USPSTF's review of the topic, i.e., change in clinical practice, research focus, etc.

DATES: Topic nominations should be submitted by February 23, 2006, in order to be considered for 2006–2008. AHRQ will not reply to submissions in response to the request for nominations, but will consider all topic nominations during the selection process. If a topic is selected for review by the USPSTF, the nominator will be notified by AHRQ.

ADDRESSES: Please submit nominations to: Therese Miller, DrPH, ATTN: USPSTF Topic Nominations, Center for Primary Care, Prevention & Clinical Partnerships, Agency for Healthcare Research and Quality, 540 Gaither Road,

Rockville, MD 20850, Fax: 301.427.1597, E-mail: *tmiller@ahrg.gov*.

FOR FURTHER INFORMATION CONTACT: Therese Miller at *tmiller@ahrq.gov* or Gloria Washington at *gwashing@ahrq.gov.*

Arrangement For Public Inspection: All nominations will be available for public inspections by appointment at the Center for Primary Care, Prevention & Clinical Partnerships, 301.427.1500, weekdays between 10 a.m. and 5 p.m. (eastern time).

SUPPLEMENTARY INFORMATION:

Background

Under Title IX of the Public Health Service Act, AHRQ is charged with enhancing the quality, appropriateness and effectiveness of health care services and access to such services. AHRQ accomplishes these goals through scientific research and promotion of improvements in clinical practice, including prevention of diseases and other health conditions and improvements in the organization, financing and delivery of health care services (42 U.S.C. 299–299c–7 as amended by Pub. L. 106–129 (1999)).

The United States Preventive Services Task Force (USPSTF) is an independent expert panel, first established in 1984 under the auspices of the U.S. Public Health Service. Currently, under AHRQ's authorizing legislation noted above, the Director of AHRQ is responsible for convening the USPSTF to be composed of individuals with appropriate expertise. The mission of the Task Force is to rigorously evaluate the effectiveness of critical preventive services and to formulate recommendations for primary care clinicians regarding the appropriate provision of preventive services. The USPSTF transitioned to a standing Task Force in 2001. Current Task Force recommendations and associated evidence reviews are available at *http://www.preventiveservices.ahrq.gov.*

Topic Nomination Solicitation

The purpose of this solicitation for new topics by AHRQ and the USPSTF is to create a balanced portfolio of relevant topics for the current Task Force library. The library is based on populations, types of services (screening, counseling, preventive medications), and disease types (cancer; heart and vascular disease; injury and violence-related disorders; infectious diseases; mental disorders and substance abuse; metabolic, nutritional and endocrine diseases; musculoskeletal conditions; obstetric and gynecological conditions; pediatric disorders; and, vision and hearing disorders). Selection of suggested topics will be made on the basis of qualifications of nominations as outlined above (see basic topic nomination requirements) and the current expertise of the USPSTF.

U.S. Preventive Services Task Force

	Type of preventive service
Topics Currently Under Review:	
Additional Risk Factors for Intermediate CHD Risk.	S
Aspirin Primary Prevention of CHD.	PM
Aspirin Prophylaxis in Pregnancy.	PM
Aspirin/NSAIDs to prevent Colorectal Cancer.	PM
Bacterial Vaginosis in Pregnancy.	S
Breast Cancer	S/PM
Carotid Artery Stenosis	S
Chlamydial Infection	S
Colorectal Cancer	S
Depression in Adults	S
Drug Misuse	S
Dyslipidemia in Adults and Children.	S
Gestational Diabetes Mellitus	S
Hearing Impairment in Elderly	S
Hearing Impairment Newborn	S
Hemochromatosis	S
Hip Dysplasia	S
HIV & Other Sexually Transmitted Diseases.	C
Iron Deficiency Anemia, including iron prophylaxis.	S
Lead Levels in Childhood & Pregnancy.	S
Motor Vehicle Occupant Injuries.	C
Obesity in Adults	S/C
Osteoporosis to prevent Fractures.	S
Skin Cancer	S/C
Speech & Language Delay	S
Thyroid Cancer	S
Topics Recently Reviewed:	
Abdominal Aortic Aneurysm	S
Adolescent Idiopathic Scoliosis	S
Alcohol Misuse	C
Bladder Cancer	S
BRCA 1 & 2	S
Breastfeeding	C
Cervical Cancer	S
Coronary Heart Disease screening by EKG, ETT, EBCT.	S
Dementia	S
Dental Caries in Preschool Children.	S
Diabetes Mellitus Type 2	S
Family Violence	S
Genital Herpes Simplex	S
Glaucoma	S
Gonorrhea	S
Hepatitis B Virus Infection	S
Hepatitis C Virus Infection in Adults.	S
Healthy Diet	C
HIV Infection	S
Hypertension	S
Low Back Pain	C
Lung Cancer	S
Obesity in Children	S
Oral Cancer	S
Ovarian Cancer	S
Pancreatic Cancer	S
Peripheral Arterial/Vascular Disease.	S
Physical Activity	C
Postmenopausal Hormone Prophylaxis (HRT).	PM
Prostate Cancer	S
Rh Incompatibility	S
Suicide Risk	S
Syphilis	S
Testicular Cancer	S
Thyroid Disease	S
Visual Impairment in Children	S

Type of Preventive Service: S = Screening; C = Counseling; PM = Preventive Medications.

Dated: January 17, 2006.

Carolyn M. Clancy,

Director.

[FR Doc. 06–612 Filed 1–23–06; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meetings

In accordance with section 10(d) of the Federal Advisory Committee Act as amended (5 U.S.C., Appendix 2), the Agency for Healthcare Research and Quality (AHRQ) announces meetings of scientific peer review groups. The subcommittees listed below are part of the Agency's Health Services Research Initial Review Group Committee.

The subcommittee meetings will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications are to be reviewed and discussed at these meetings. These discussions are likely to involve information concerning individuals associated with the applications, including assessments of their personal qualifications to conduct their proposed projects. This information is exempt from mandatory disclosure under the above-cited statutes.

1. Name of Subcommittee: Health Care Technology and Decision Sciences.

   Date: February 2, 2006 (Open from 8 a.m. to 8:15 a.m. on February 2 and closed for remainder of the meeting).

2. Name of Subcommittee: Health Research Dissemination and Implementation.
   Date: February 16, 2006 (Open from 8 a.m. to 8:15 a.m. on February 16 and closed for remainder of the meeting).
3. Name of Subcommittee: Health Care Quality and Effectiveness Research.
   Date: February 23, 2006 (Open from 8 a.m. to 8:15 a.m. on February 23 and closed for remainder of the meeting).
4. Name of Subcommittee: Health Research Training.
   Date: February 27–28, 2006 (Open from 9 a.m. to 9:15 a.m. on February 27 and closed for remainder of the meeting).
5. Name of Subcommittee: Health Systems Research.
   Date: February 28, 2006 (Open from 9 a.m. to 9:15 a.m. on February 28 and closed for remainder of the meeting).

All the meetings above will take place at: Agency for Healthcare Research and Quality, John Eisenberg Conference Center, 540 Gaither Road, Rockville, Maryland 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the nonconfidential portions of the meetings should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Suite 2000, Rockville, Maryland 20850, Telephone (301) 427–1554.

Agenda items for these meetings are subject to change as priorities dictate.

This notice is being published less than 15 days prior to the February 2 meeting, due to the time constraints of reviews and funding cycles.

Dated: January 13, 2006.

Carolyn M. Clancy,

Director.

[FR Doc. 06–611 Filed 1–23–06; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–06–0576]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–4766 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576)—Revision—Office of the Director (OD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) specifies that the Secretary of Health and Human Services (HHS) shall provide for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. The Act specifies that entities that possess, use, and transfer these select agents register with the HHS Secretary. The HHS Secretary has designated CDC as the agency responsible for collecting this information.

CDC is requesting continued OMB approval to collect this information through the use of five separate forms. These forms are: (1) Application for Registration, (2) Request to Transfer Select Agent or Toxin, (3) Report of Theft, Loss, or Release of Select Agent and Toxin, (4) Report of Identification of Select Agent or Toxin, and (5) Request for Exemption.

The Application for Registration (42 CFR, 73.7(d)) is used by entities to register with CDC. The Application for Registration requests facility information; a list of select agents or toxins in use, possession, or for transfer by the entity; characterization of the select agent or toxin; and laboratory information. Estimated average time to complete this form is 3 hours, 45 minutes for an entity with one principal investigator working with one select agent or toxin. CDC estimates that entities will need an additional 45 minutes for each additional investigator or agent. In our regulatory analysis, we have estimated that 70% of the 350 entities have 1–3 principal investigators, 15% have 5 principal investigators, and 15% have 10 principal investigators. We have used these figures to calculate the burden for this section. Estimated burden for the Application for Registration is 2,191 hours.

Entities may amend their registration (42 CFR, 73.7(h)(1)) if any changes occur in the information submitted to CDC. To apply for an amendment to a certificate of registration, an entity must obtain the relevant portion of the application package and submit the information requested in the package to CDC. Estimated time to amend a registration package is 1 hour.

The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) is used by entities requesting transfer of a select agent or toxin to their facility and by the entity transferring the agent. CDC revised the Request to Transfer Select Agent or Toxin form by removing the requirement that entities provide written notice within five business days when select agents or toxins are consumed or destroyed after a transfer. Estimated average time to complete this form is 1 hour, 30 minutes.

The Report of Theft, Loss, or Release of Select Agent and Toxin form (42 CFR 73.19(a)(b)) must be completed by entities whenever there is theft, loss, or release of a select agent or toxin. Estimated average time to complete this form is 1 hour.

The Report of Identification of Select Agent or Toxin form 42 CFR 73.5(a)(b) and 73.6(a)(b)) is used by clinical and diagnostic laboratories to notify CDC that select agents or toxins identified as the result of diagnostic or proficiency testing have been disposed of in a proper manner. In addition, the form is used by Federal law enforcement agencies to report the seizure and final disposition of select agents and toxins. Estimated average time to complete this form is 1 hour.

The Request for Exemption form (42 CFR 73.5 (d)(e) and 73.6 (d)(e)) is used by entities that are using an investigational product that are, bear, or contain select agents or toxins or in cases of public health emergency. Estimated average time to complete this form is 1 hour.

In addition to the standardized forms, this regulation also outlines situations in which an entity must notify or may make a request of the HHS Secretary in writing. An entity may apply to the HHS Secretary for an expedited review of an individual by the Attorney General (42 CFR 73.10(e)). To apply for this expedited review, an entity must submit a request in writing to the HHS Secretary establishing the need for such action. The estimated time to gather the information and submit this request is 30 minutes. CDC has not developed standardized forms to use in the above situations. Rather, the entity should

provide the information as requested in the appropriate section of the regulation.

An entity may also apply to the HHS Secretary for an exclusion of an attenuated strain of a select agent or toxin that does not pose a severe threat to public health and safety (42 CFR 73.3(e)(1) and 73.4(e)(1)). The estimated time to gather the information and submit this request is 1 hour.

As part of the requirements of the Responsible Official, the Responsible Official is required to conduct regular inspections (at least annually) of the laboratory where select agents or toxins are stored. Results of these self-inspections must be documented (42 CFR 73.9(a)(5)). CDC estimates, that, on average, such documentation will take 1 hour.

As part of the training requirements of this regulation, the entity is required to record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training (42 CFR 73.15(c)). Estimated time for this documentation is 2 hours per principal investigator.

An individual or entity may request administrative review of a decision denying or revoking certification of registration or an individual may appeal a denial of access approval (42 CFR 73.20). This request must be made in writing and within 30 calendar days after the adverse decision. This request should include a statement of the factual basis for the review. CDC estimates the time to prepare and submit such a request is 4 hours.

Finally, an entity must implement a system to ensure that certain records and databases are accurate and that the authenticity of records may be verified (42 CFR 73.17(b)). The time to implement such a system is estimated to average 4 hours.

The cost to respondents is their time to complete the forms and comply with the reporting and recordkeeping components of the Act plus a one-time purchase of a file cabinet (estimated cost $400) to maintain records. The total estimated annualized burden hours are 7,785.

ESTIMATED ANNUALIZED BURDEN HOURS

CFR reference	Data collection instrument	Number of respondents	Responses per respondent	Average burden per response
73.7(d)	Registration application form	350	1	3.75
73.7(d)	Additional investigators	245	2	45/60
73.7(d)	Additional investigators	53	4	45/60
73.7(d)	Additional investigators	52	9	45/60
73.7(h)(1)	Amendment to registration application	350	2	1
73.19(a)(b)	Report of theft, loss, or release	12	1	1
73.5 & 73.6 (d–e)/ 73.3 & 73.4 (e)(1).	Request for exemption form/exclusion	17	1	1
73.16	Request to transfer	350	2	1.5
73.5 & 73.6 (a)(b)	Report of identification	325	4	1
73.10(e)	Request expedited review	10	1	30/60
73.9(a)(5)	Documentation of self-inspection	350	1	1
73.15(c)	Documentation of training	350	1	2
73.20	Administrative review	15	1	4
73.17	Ensure secure recordkeeping system	350	1	4

Dated: January 18, 2006.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–808 Filed 1–23–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice concerning the final effect of the HHS decision to designate a class of employees at the Linde Ceramics Plant, in Tonawanda, New York, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On December 8, 2005, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

Atomic weapons employees who worked at the Linde Ceramics Plant from October 1, 1942, through October 31, 1947, and who were employed for a number of work days aggregating at least 250 work days either solely under this employment or in combination with work days occurring within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

This designation became effective on January 7, 2006, as provided for under 42 U.S.C. 7384*l*(14)(C). Hence, beginning on January 7, 2006, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV.*

Dated: January 17, 2006.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 06–593 Filed 1–23–06; 8:45 am]

BILLING CODE 4163–19–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Ohio State Plan Amendments 05–07 and 05–020

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on February 28, 2006, in Suite #500, 233 N. Michigan Avenue, Minnesota Conference Room, Chicago, IL 60202, to reconsider CMS' decision to disapprove Ohio State plan amendments 05–07 and 05–020.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by February 8, 2006.

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, CMS, Lord Baltimore Drive, Mail Stop LB–23–20, Baltimore, Maryland 21244. Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS' decision to disapprove Ohio State plan amendments (SPAs) 05–07 and 05–020, which were submitted on August 1, 2005, and September 1, 2005, respectively. Both SPAs were disapproved on October 28, 2005. Under SPAs 05–07 and 05–020, Ohio sought to implement the Medicaid School Program.

The amendments were disapproved because they do not comport with the requirements of section 1902(a) of the Social Security Act (the Act) and implementing regulations. The specific reasons for disapproval are identified below.

Under section 1902(a)(10) of the Act, a State plan must provide for making medical assistance available to eligible individuals. ''Medical assistance,'' as defined in section 1905(a) of the Act, does not include habilitation services. After CMS determined that habilitation services were not properly included within the scope of the statutory category of rehabilitation services, the Omnibus Budget Reconciliation Act of 1989 (OBRA–89) ''grandfathered'' certain States, including Ohio, to provide habilitation services under previously approved State plan provisions as part of the Medicaid rehabilitation benefit. However, Ohio formally terminated its habilitation services (known as the ''Community Alternative Funding System,'' or CAFS program) in SPA 05–008 and, thus, is no longer ''grandfathered'' based on its previously approved State plan provision. Because there is no provision of the State's Medicaid plan as approved on or before June 30, 1989, that provides coverage of habilitation services in the State's current approved plan, the provisions of section 6411(g)(1)(A) of OBRA–89, that prohibit the Secretary from withholding, suspending, disallowing, or denying Federal financial participation for habilitation services, no longer apply.

In addition, the SPAs do not comply with the requirements of section 1902(a)(1) of the Act that services under the plan be available statewide. Under the SPAs, services would be covered only for select groups of students in participating schools but services would not be available to other eligible individuals. Because not all parts of the State may have participating schools, the SPAs violate statewideness requirements. The restricted availability of services also violates the requirements of section 1902(a)(10)(B) of the Act that services available to each individual within a Medicaid eligibility group must be comparable in amount, duration, and scope (and that services available to categorically needy groups cannot be less in amount, duration, and scope than those available to the medically needy). The SPAs are not consistent with comparability requirements because the services are available only to select groups of students.

Additionally, these SPAs explicitly deny the provision of Medicaid fair hearing requests for individuals who are denied services. This provision is at variance with section 1902(a)(3) of the Act and Federal regulations at 42 CFR 431.200(a) which require that a State plan ''provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.''

In addition, the State did not demonstrate that the proposed payment methodology would comply with the statutory requirements of sections 1902(a)(2), 1902(a)(30)(A), and 1903(a)(1) of the Act, which require that the State plan assure adequate funding for the non-Federal share of expenditures from State or local sources; that State or local sources have methods and procedures to assure that payments are consistent with efficiency, economy, and quality of care; and that Federal matching funds are only available for actual expenditures made by States for services under the approved plan. The State did not respond fully to CMS' requests for information concerning State payment and funding issues. Absent such information, CMS could not determine whether the proposed SPA would operate in compliance with all applicable requirements of section 1902(a) of the Act.

Finally, for Ohio SPA 05–020 alone, the State did not show compliance with section 1902(a)(4) of the Act, which specifies that the State plan must provide for such methods of administration as are found by the Secretary to be necessary for the proper and efficient administration of the plan. Pursuant to this provision, States must include in their State plans all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation. Absent information on the methodology used to develop the fee schedules, this requirement is not met.

For the reasons cited above, and after consultation with the Secretary, as required by 42 CFR 430.15(c)(2), Ohio SPAs 05–07 and 05–020 were disapproved.

Section 1116 of the Act and Federal regulations at 42 CFR Part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. CMS is required to publish a copy of the notice to a State Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Ohio announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Mr. Jim Petro, Office of the Attorney General, Health & Human Services Section, 30 E. Broad Street, 26th Floor, Columbus, OH 43215–3400.

Dear Mr. Petro:

I am responding to your request for reconsideration of the decision to disapprove Ohio State plan amendments (SPAs) 05–07 and 05–020, which were submitted on August 1, 2005, and September 1, 2005, respectively, and disapproved on October 28, 2005.

Under SPAs 05–07 and 05–020, Ohio was seeking to implement the Medicaid School Program.

The amendments were disapproved because they did not comport with the requirements of section 1902(a) of the Social Security Act (the Act) and implementing regulations. The specific reasons for disapproval are identified below.

Under section 1902(a)(10) of the Act, a State plan must provide for making medical assistance available to eligible individuals. ''Medical assistance,'' as defined in section 1905(a) of the Act, does not include habilitation services. After the Centers for Medicare & Medicaid Services (CMS) determined that habilitation services were not properly included within the scope of the statutory category of rehabilitation services, the Omnibus Budget Reconciliation Act of 1989 (OBRA–89) ''grandfathered'' certain States, including Ohio, to provide habilitation services under previously approved State plan provisions as part of the Medicaid rehabilitation benefit. However, Ohio formally terminated its habilitation services (known as the ''Community Alternative Funding System,'' or CAFS program) in SPA 05–008 and, thus, is no longer ''grandfathered'' based on its previously approved State plan provision. Because there is no provision of the State's Medicaid plan as approved on or before June 30, 1989, that provides coverage of habilitation services in the State's current approved plan, the provisions of section 6411(g)(1)(A) of OBRA–89, that prohibit the Secretary from withholding, suspending, disallowing, or denying Federal financial participation for habilitation services, no longer apply.

In addition, the SPAs do not comply with the requirements of section 1902(a)(1) of the Act that services under the plan be available statewide. Under the SPAs, services would be covered only for select groups of students in participating schools but services would not be available to other eligible individuals. Because not all parts of the State may have participating schools, the SPAs violate statewideness requirements. The restricted availability of services also violates the requirements of section 1902(a)(10)(B) of the Act that services available to each individual within a Medicaid eligibility group must be comparable in amount, duration, and scope (and that services available to categorically needy groups cannot be less in amount, duration, and scope than those available to the medically needy). The SPAs are not consistent with comparability requirements because the services are available only to select groups of students.

Additionally, these SPAs explicitly deny the provision of Medicaid fair hearing requests for individuals who are denied services. This provision is at variance with section 1902(a)(3) of the Act and Federal regulations at 42 CFR 431.200(a) which require that a State plan ''provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.''

In addition, the State did not demonstrate that the proposed payment methodology would comply with the statutory requirements of sections 1902(a)(2), 1902(a)(30)(A), and 1903(a)(1) of the Act, which require that the State plan assure adequate funding for the non-Federal share of expenditures from State or local sources; that State or local sources have methods and procedures to assure that payments are consistent with efficiency, economy, and quality of care; and that Federal matching funds are only available for actual expenditures made by States for services under the approved plan. The State did not respond fully to CMS' requests for information concerning State payment and funding issues. Absent such information, CMS could not determine whether the proposed SPA would operate in compliance with all applicable requirements of section 1902(a) of the Act.

Finally, for Ohio SPA 05–020 alone, the State did not show compliance with section 1902(a)(4) of the Act, which specifies that the State plan must provide for such methods of administration as are found by the Secretary to be necessary for the proper and efficient administration of the plan. Pursuant to this provision, States must include in their State plans all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation. Absent information on the methodology used to develop the fee schedules, this requirement is not met.

For the reasons cited above, and after consultation with the Secretary, as required by 42 CFR 430.15(c)(2), Ohio SPAs 05–07 and 05–020 were disapproved.

I am scheduling a hearing on your request for reconsideration to be held on February 28, 2006, at Suite #500, 233 N. Michigan Avenue, Minnesota Conference Room, Chicago, IL 60202, to reconsider the decision to disapprove SPA 05–07 and 05–020. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR Part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer at (410) 786–2055. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing.

Sincerely,

Mark B. McClellan, MD., PhD.

Section 1116 of the Social Security Act (42 U.S.C. 1316); 42 CFR 430.18.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: January 13, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E6–788 Filed 1–23–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0396]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 23, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail,

including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level—(OMB Control Number 0910–0430)—Extension

This information collection approval request is for an FDA guidance on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that cannot be resolved at the division level. The guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue(s) presented. The guidance provides information on how the agency will interpret and apply provisions of the existing regulations regarding internal agency review of decisions (§ 10.75 (21 CFR 10.75)) and dispute resolution during the investigational new drug (IND) process (21 CFR 312.48) and the new drug application/abbreviated new drug application (NDA/ANDA) process (21 CFR 314.103). In addition, the guidance provides information on how the agency will interpret and apply the specific Prescription Drug User Fee Act (PDUFA) goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the agency, CDER, and CBER. All agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in parts 312 (OMB Control No. 0910–0014), 314 (OMB Control No. 0910–0001), and part 601 (21 CFR part 601) (OMB Control No. 0910–0338), which specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. While FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the dispute. The guidance describes the following collection of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations (§§ 312.23(d), 314.50, 314.94, and 601.2) state that information provided to the agency as part of an IND, NDA, ANDA, or BLA is to be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571, OMB Control No. 0910–0014, expires January 31, 2006; and FDA Form 356h, OMB Control No. 0910–0338, expires August 31, 2005.

In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted as an amendment in this manner for two reasons: To ensure that each request is kept in the administrative file with the entire underlying application and to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance recommends that the following information should be submitted to the appropriate center with each request for dispute resolution so that the center may quickly and efficiently respond to the request: (1) A brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (i.e., scientific, procedural, or both), possible solutions based on information in the administrative file, whether informal dispute resolution was sought prior to the formal appeal, whether advisory committee review is sought, and the expected outcome; (2) a statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last agency official that attempted to formally resolve the matter; (3) a list of documents in the administrative file, or additional copies of such documents, that are deemed necessary for resolution of the issue(s); and (4) a statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The information that the agency suggests submitting with a formal request for dispute resolution consists of: (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) the documents previously submitted to FDA under an OMB approved collection of information.

Based on FDA's experience with dispute resolution, the agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance will be minimal.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biological product regulated by the agency under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act who requests formal resolution of a scientific or procedural dispute.

Burden Estimate: Provided in table 1 of this document is an estimate of the annual reporting burden for requests for dispute resolution. Based on data collected from review divisions and offices within CDER and CBER, FDA estimates that approximately 8 sponsors and applicants (respondents) submit requests for formal dispute resolution to CDER annually and approximately 1 respondent submits requests for formal dispute resolution to CBER annually.

The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. FDA estimates that CDER receives approximately 10 requests annually and CBER receives approximately 1 request annually. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 88 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

In the **Federal Register** of October 24, 2005, (70 FR 61453), FDA announced the availability of the draft guidance and requested comments for 60 days on the information collection. No comments were received on this information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Requests for Formal Dispute Resolution	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	8	1.25	10	8	80
CBER	1	1	1	8	8
Total					88

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 13, 2006.

Jeffrey Shuren,

Assistant Commssioner for Policy.

[FR Doc. E6–763 Filed 1–23–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0021]

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the regulations which state that protocols for samples of biological products must be submitted to the agency.

DATES: Submit written or electronic comments on the collection of information by March 27, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Request for Samples and Protocols (OMB Control Number 0910–0206)—Extension)

Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that the biologics licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), FDA may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot along with the protocols showing the results of applicable tests prior to marketing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols

for specific licensed biological products: §§ 660.6 (21 CFR 660.6) (Antibody to Hepatitis B Surface Antigen), 660.36 (21 CFR 660.36) (Reagent Red Blood Cells), and 660.46 (21 CFR 660.46) (Hepatitis B Surface Antigen).

Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by the Center for Biologics Evaluation and Research (CBER). After official release is no longer required, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires that a protocol contain information including, but not limited to, manufacturing records, test records, and test results. Section 660.36 (b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to FDA at the time of initial distribution of each lot.

Section 660.46(a) provides requirements for the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Samples and protocols are required by FDA to help ensure the safety, purity, or potency of the product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (*e.g.*, Albumin, Plasma Protein Fraction, and specified biotechnology and specified synthetic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for the protocols that are required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously in this document. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products including submissions for lot release, surveillance, licensing, or export. Based on information obtained from FDA's database system, approximately 70 manufacturers submitted samples and protocols in fiscal year (FY) 2005, under the regulations cited previously in this document. FDA estimates that 65 manufacturers submitted protocols under § 610.2, and 4 manufacturers submitted protocols under the regulations (§§ 660.6 and 660.46) for the other specific products. FDA received no submissions under § 660.36, however FDA is using the estimate of one protocol submission in the event one is submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2005, which totaled 4,930, for the various submission requirements of samples and protocols for the licensed biological products. The rate of final actions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the hours per response are based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the protocol than under § 610.2.

FDA estimates the burden of this collection of information as follows:

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.2	65	74.1	4,816	3	14,448
660.6(b)	3	26	78	5	390
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	1	35	35	5	175
Total	70		4,930		15,019

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–764 Filed 1–23–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0395]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 23, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Formal Meetings with Sponsors and Applicants for Prescription Drug User Fee Act Products (OMB Control Number 0910–0429)—Extension

This information collection approval request is for an FDA guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of Prescription Drug User Fee Act (PDUFA) products. The guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The guidance provides information on how the agency will interpret and apply section 119(a) of the Food and Drug Administration Modernization Act (the Modernization Act), specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82 (21 CFR 312.47 and 312.82)).

The guidance describes two collections of information: The submission of a meeting request containing certain information and the submission of an information package in advance of the formal meeting. Agency regulations at § 312.47(b)(1)(ii), (b)(1)(iv), and (b)(2) describe information that should be submitted in support of a request for an End of Phase 2 meeting and a Pre New Drug Application (NDA) meeting. The information collection provisions of § 312.47 have been approved by OMB (OMB control number 0910–0014). However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting additional estimates for OMB approval.

I. Request for a Meeting

Under the guidance, a sponsor or applicant interested in meeting with the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) should submit a meeting request to the appropriate FDA component as an amendment to the underlying application. FDA regulations (§§ 312.23, 314.50, and 601.2 (21 CFR 312.23, 314.50, and 601.2)) state that information provided to the agency as part of an Investigational New Drug Application (IND), NDA, or Biological License Application (BLA) must be submitted with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571, OMB control number 0910–0014; and FDA Form 356h, OMB control number 0910–0338, expires September 30, 2008.

In the guidance document, CDER and CBER ask that a request for a formal meeting be submitted as an amendment to the application for the underlying product under the requirements of §§ 312.23, 314.50, and 601.2; therefore, requests should be submitted to the agency with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted in this manner for the following two reasons: (1) To ensure that each request is kept in the administrative file with the entire underlying application, and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the agency to monitor progress on the activities attendant to scheduling and holding a formal meeting and to ensure that appropriate steps will be taken in a timely manner.

Under the guidance, the agency requests that sponsors and applicants include in meeting requests certain information about the proposed meeting. Such information includes the following:

- Information identifying and describing the product,
- The type of meeting being requested,
- A brief statement of the purpose of the meeting,
- A list of objectives and expected outcomes from the meeting,
- A preliminary proposed agenda,
- A draft list of questions to be raised at the meeting,
- A list of individuals who will represent the sponsor or applicant at the meeting,
- A list of agency staff requested to be in attendance,
- The approximate date that the information package will be sent to the agency, and
- Suggested dates and times for the meeting.

This information will be used by the agency to determine the utility of the meeting, to identify agency staff necessary to discuss proposed agenda items, and to schedule the meeting.

II. Information Package

A sponsor or applicant submitting an information package to the agency in advance of a formal meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the sponsor, applicant, or agency. The agency recommends that information packages generally include the following:

- Identifying information about the underlying product;
- A brief statement of the purpose of the meeting;
- A list of objectives and expected outcomes of the meeting;

- A proposed agenda for the meeting;
- A list of specific questions to be addressed at the meeting;
- A summary of clinical data that will be discussed (as appropriate);
- A summary of preclinical data that will be discussed (as appropriate); and
- Chemistry, manufacturing, and controls information that may be discussed (as appropriate).

The purpose of the information package is to provide agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. Although FDA reviews similar information in the meeting request, the information package should provide updated data that reflect the most current and accurate information available to the sponsor or applicant. The agency finds that reviewing such information is critical to achieving a productive meeting.

The collection of information described in the guidance reflects the current and past practice of sponsors and applicants to submit meeting requests as amendments to INDs, NDAs, and BLAs and to submit background information prior to a scheduled meeting. Agency regulations currently permit such requests and recommend the submission of an information package before an End of Phase 2 meeting (§§ 312.47(b)(1)(ii) and (b)(1)(iv)) and a Pre NDA meeting (§ 312.47(b)(2)).

Description of respondents: A sponsor or applicant for a drug or biological product who requests a formal meeting with the agency regarding the development and review of a PDUFA product.

Burden Estimate: Provided in the following paragraphs is an estimate of the annual reporting burden for the submission of meeting requests and information packages under the guidance.

III. Request For a Formal Meeting

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 713 sponsors and applicants (respondents) request approximately 1,783 formal meetings with CDER annually and approximately 164 respondents request approximately 286 formal meetings with CBER annually regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be approximately 10 hours. Based on FDA's experience, the agency expects it will take respondents this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting.

IV. Information Package

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 615 respondents submitted approximately 1,365 information packages to CDER annually and approximately 132 respondents submitted approximately 208 information packages to CBER annually prior to a formal meeting regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package in accordance with the guidance, is estimated to be approximately 18 hours. Based on FDA's experience, the agency expects it will take respondents this amount of time to gather and copy brief statements about the product, a description of the details for the anticipated meeting, and data and information that generally would already have been compiled for submission to the agency.

As stated earlier, the guidance provides information on how the agency will interpret and apply section 119(a) of the Modernization Act, specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82). The information collection provisions in § 312.47 concerning End of Phase 2 meetings and Pre NDA meetings have been approved by OMB (OMB control number 0910–0014). However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting for OMB approval these additional estimates.

In the **Federal Register** of October 24, 2005 (70 FR 61445), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Meeting Requests and Information Packages	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Meeting Requests					
CDER	713	2.50	1,783	10	17,830
CBER	164	1.74	286	10	2,860
Total					20,690
Information Packages					
CDER	615	2.22	1,365	18	24,570
CBER	132	1.58	208	18	3,744
Total					28,314
Grand Total					49,004

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–765 Filed 1–23–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0296]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Good Laboratory Practice Regulations for Nonclinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Good Laboratory Practice Regulations for Nonclinical Studies'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 4, 2005 (70 FR 364) the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0119. The approval expires on April 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: January 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–768 Filed 1–23–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Fogarty International Center Advisory Board.

Date: February 6–7, 2006.

Closed: February 6, 2006, 1 p.m. to Adjournment.

Agenda: To review and evaluate grant applications and proposals.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Open: February 7, 2006, 8:30 a.m. to 5 p.m.

Agenda: A report of the FIC Director on updates and overviews of new FIC initiatives. Topics to be discussed: The Disease Control Priorities Project: An Update.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Contact Person: Jean L. Flagg-Newton, PhD, Special assistant to the Director, FIC, Fogarty International Center, National Institutes of Health, 9000 Rockville Pike, Building 31, Room B2C29, Bethesda, MD 20892. (301) 496–2968. *flaggnej@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: *http://www.nih.gov/fic/about/advisory.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–652 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commerical property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group Subcommittee A—Cancer Centers.

Date: April 5, 2006.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications

Place: Wyndham City Center Hotel, 1143 New Hampshire Ave., NW., Washington, DC 20037.

Contact Person: David E. Maslow, PhD, Scientific Review Administrator, Resources and Training Review Branch, Division of

Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8117, Bethesda, MD 20892–7405, (301) 496–2330, *dm65y@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 10, 2006

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–643 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel CA06–001 (Cancer Detection) and CA06–004/CA06–007 (Cancer Sample Preparation).

Date: March 9–10, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Timothy C. Meeker, MD, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8103, Bethesda, MD 20892, (301) 594–1279, *meekert@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 10, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–644 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commerical property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Cancer Therapeutics.

Date: February 15, 2006.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Shakeel Ahmad, PhD, Scientific Review Administrator, Research Programs Review Branch, National Cancer Institute, Division of Extramural Activities, 6116 Executive Blvd., Bethesda, MD 20892, (301) 594–0114, *ahmads@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 10, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–645 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, February 27, 2006, 8 a.m. to February 27, 2006, 5 p.m., Ramada Inn Rockville, 1775 Rockville Pike, Rockville, MD, 20852 which was published in the **Federal Register** on December 21, 2005, 70FR75824.

The meeting is amended to change the meeting format to a teleconference, the meeting time to 11 a.m.–4 p.m. and the meeting location to 6130 Executive Blvd., Conference Room F in Rockville, MD and to remove SBIR Topic 206. The meeting is closed to the public.

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–648 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Open: February 7, 2006, 8:30 a.m. to 4:30 p.m.

Agenda: Program reports and presentations; Business of the Board.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327. (301) 496–5147.

Name of Committee: National Cancer Advisory Board.

Closed: February 7, 2006, 4:30 p.m. to 6 p.m.

Agenda: Review of grant applications.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327. (301) 496–5147.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/ncab.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 12, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–663 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Initial Review Group; Comparative Medicine Review Committee.

Date: February 7–8, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: John R. Glowa, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6701 Democracy Boulevard, Room 1078–MSC 4874, Bethesda, MD 20892–4874. 301–435–0807. *glowaj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–658 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Initial Review Group; Clinical Research Review Committee.

Date: February 8–9, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mohan Viswanathan, PhD, Deputy Director, National Center for Research Resources, or National Institutes of Health, 6701 Democracy Blvd., Room 1084, MSC 4874, 1 Democracy Plaza, Bethesda, MD 20892–4874. 301–435–0829. *mv10f@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–659 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel.

Date: February 22–23, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Carol Lambert, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1076, Bethesda, MD 20892–4874 (301) 435–0814. *lambert@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–660 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provision set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel. Resource-Related Research Projects (R24).

Date: February 9, 2006.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Shelley S. Sehnert, PhD, Scientific Review Administrator, Review Branch, NIH/NHLBI, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892–7924. 301/435–0303. *ssehnert@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 13, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–640 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of person privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel. Exploratory/Developmental Grants (R21).

Date: January 26, 2006.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Valerie L. Prenger, PhD, Health Scientist Administrator, Review Branch, Room 7214, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892–7924. (301) 435–0270. *prengerv@nhlbi.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–650 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel Effects of Inhaled Florida Red Tide Brevetoxins.

Date: February 10, 2006.

Time: 9 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Linda K. Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, 919/541–1307.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: January 12, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–637 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b9c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group Health Services Research Review Subcommittee.

Date: March 8–9 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Lorraine Gunzerath, PhD, MBA, Scientific Review Administrator, National Institute on Alcohol Abuse and Alcoholism, Office of Extramural Activities, Extramural Project Review Branch, 5635 Fishers Lane, Room 3043, Bethesda, MD 20892–9304, Bethesda, MD 20892–9304, 301–443–2369, *lgunzera@mail.nih.gov.*

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date: March 8, 2006.

Time; 8 a.m. to 9 a.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Lorraine Gunzerath, PhD, MBA, Scientific Review Administrator, National Institute on Alcohol Abuse and Alcoholism, Office of Extramural Activities, Extramural Project Review Branch, 5635 Fishers Lane, Room 3043, Bethesda, MD 20892–9304, 301–443–2369, *lgunzera@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: January 13, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–638 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussion could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Depression Treatment Follow-up Study.

Date: February 3, 2006.

Time: 12 p.m. to 1:30 p.m.

Agenda: to review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: David I. Sommers, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6144, MSC 9606, Bethesda, MD 20892–9606. 301–443–7861. *dsommers@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: January 13, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–639 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Training Grant and Career Development Review Committee NST.

Date: January 19–20, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Jurys Doyle, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

Contact Person: Raul A. Saavedra, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, NSC; 6001 Executive Blvd., Ste. 3208, Bethesda, MD 20892–9529, 301–496–9223, *saavedrrAninds.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders B.

Date: February 21–22, 2006.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance, Washington, DC Hotel, 999 Ninth Street, NW., Washington, DC 20001.

Contact Person: W. Ernest Lyons, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–4056.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders C.

Date: February 22, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance, Washington, DC Hotel, 999 Ninth Street, NW., Washington, DC 20001–4427.

Contact Person: Andrea Sawczuk, DDS, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, 6001 Executive Boulevard, Room #3208, Bethesda, MD 20892, 301–496–0660, *sawczuka@ninds.nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders A.

Date: March 2–3, 2006.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Villa Florence Hotel, 450 Powell St., San Francisco, CA 94102.

Contact Person: Richard D. Crosland, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS Neuroscience Center, 6001 Executive Blvd, Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–9223.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders.

Date: March 13–14, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Radisson Poco Diablo Resort, 1752 S. Hwy 179, Sedona, AZ 86336.

Contact Person: Katherine M. Woodbury, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd, Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–9223.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neuroscience, National Institutes of Health, HHS)

Dated: January 13, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–642 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposal and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel. Maintenance and Operation of a Chemical Synthesis Facility.

Date: February 9, 2006.

Time: 12 p.m. to 1:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Hameed Khan, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892. 301–435–6902. *khanh@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–649 Filed 1–23–05; 8:45am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel. Minority Institutions' Drug Abuse Research Development Program (MIDARP) Meeting.

Date: February 8, 2006.

Time: 9 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mark Swieter, PhD, Chief, Training and Special Projects Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6101 Executive Boulevard, Suite 220, Bethesda, MD 20892–8401. (301) 435–1389. *ms80x@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–651 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel. Development of State-of-the-Art Mechanisms for Epidemiologial Research (Phase I SBIR).

Date: January 26, 2006.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Eric Zatman, Contract Review Specialist, Office of Extramural affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401. (301) 435–1438.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel. E-Health Applications of Empirically Supported Therapies in English and/or Spanish.

Date: February 15, 2006.

Time: 9 a.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: Courtyard by Marriott Rockville, 2500 Research Boulevard, Rockville, MD 20850.

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401. (301) 435–1439. *lf33c.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–653 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussion could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group Microbiology and Infectious Diseases Research Committee.

Date: February 21–23, 2006.

Time: 8 a.m. to 6 p.m.

Agenda: to review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Annie Walker-Abbey, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institute of Health/NIAID, 6700B Rockledge Drive, RM. 3266, Bethesda, MD 20892–7616, (301)–451–2671, *aabbey@niaid.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–655 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, NIAID.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Allergy and Infectious Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIAID; Vaccine Research Center, Board of Scientific Counselors.

Date: January 30–31, 2006.

Time: January 30, 2006, 1 p.m. to 7 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Vaccine Research Center, 40 Convent Drive, Bethesda, MD 20892.

Time: January 31, 2006, 9 a.m. to 4:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Vaccine Research Center, 40 Convent Drive, Bethesda, MD 20892.

Contact Person: Gary J. Nabel, MD, PhD, Director, Vaccine Research Center, NIAID/NIH, 40 Convent Drive, Bldg 40, Room 4502, Bethesda, MD 20892. 401–496–1852. *gnabel@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–656 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Units for HIV/AIDS Clinical Trials Network (1)—FRA–05–002.

Date: February 14, 2006.

Time: 10 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Mary J. Homer, PhD, Scientific Review Administrator, Scientific Review Program, National Institute of Allergy and Infectious Diseases, DEA/NIH/DHHS, 6700–B Rockledge Drive MSC 7616 Room 3147, Bethesda, MD 20892. (301) 496–2550. *mjhomer@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–657 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; 06–51, Review R01.

Date: February 15, 2006.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: H. George Hausch, PhD, Acting Director, 45 Center Drive, Natcher Building, Rm. 4AN44F, National Inst. of Dental & Craniofacial Research, National Institutes of Health, Bethesda, MD 20892. (301) 594–2904. *george_hausch@nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; 06–46, Review R21s, R03s.

Date: February 22, 2006.

Time: 10:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Raj K Krishnaraju, PhD, MS, Scientific Review Administrator, Scientific Review Branch, National Inst of Dental & Craniofacial Research, National Institutes of Health, 45 Center Dr. Room 4AN 32J, Bethesda, MD 20892. 301–594–4864.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; 06–47, Review R21s.

Date: Feburary 24, 2006.

Time: 10:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Raj K Krishnaraju, PhD, MS, Scientific Review Administrator, Scientific Review Branch, National Inst of Dental & Craniofacial Research, National Institutes of Health, 45 Center Dr. Rm 4AN 32J, Bethesda, MD 20892. 301–594–4864.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; 06–52, Review R21s.

Date: Feburary 28, 2006.

Time: 10:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Raj K Krishnaraju, PhD, MS, Scientific Review Administrator, Scientific Review Branch, National Inst of Dental & Craniofacial Research, National Institutes of Health, 45 Center Dr. Rm 4AN 32J, Bethesda, MD 20892. 301–594–4864.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–661 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contact proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel; Translational Research (BCI).

Date: February 14, 2006.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Stanley C. Oaks, PhD, Scientific Review Administrator, Division of Extramural Activities, NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd-MSC 7180, Bethesda, MD 20892–7180. 301–496–8683. *so14s@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel; Translational Research (Laryngeal/Voice).

Date: February 14, 2006.

Time: 12:30 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Stanley C. Oaks, PhD, Scientific Review Administrator, Division of Extramural Activities, NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd-MSC 7180, Bethesda, MD 20892–7180. 301–496–8683. *so14s@nih.gov.*

Name of Committee: Communication Disorders Review Committee.

Date: February 15–16, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Washington, DC, 1400 M Street, NW., Washington, DC 20005.

Contact Person: Melissa J. Stick, PhD, MPH, Chief, Scientific Review Branch, Scientific Review Branch, Division of Extramural Research, NIDCD/NIH, 6120 Executive Blvd., Bethesda, MD 20892. 301–496–8683.

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel, Auditory Neural Prostheses.

Date: February 21, 2006.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Sheo Singh, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892. 301–496–8683. *singhs@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel; NIDCD R03 Review Meeting.

Date: February 22–23, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Shiguang Yang, PhD, DVM, Scientific Review Administrator, Division of Extramural Activities, NIDCD, NIH, 6120 Executive Blvd., Bethesda, MD 20892. 301–496–8683.

Name of Committee: National Institute on Deafness and Other Communications

Disorders Special Emphasis Panel; Vestibular Nerve Stimulation.

Date: February 22, 2006.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Sheo Singh, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892. 301–496–8683. *singhs@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel; Translational Research (Aud/Oto/Balance).

Date: February 23, 2006.

Time: 1 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Stanley C. Oaks, PhD, Scientific Review Administrator, Division of Extramural Activities, NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd-MSC 7180, Bethesda, MD 20892–7180. 301–496–8683 *so14s@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel; Cochlear Implants.

Date: February 24, 2006.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Sheo Singh, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892. 301–496–8683. *singhs@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel; CDRC Conflicts.

Date: February 28, 2006.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Sheo Singh, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892. 301–496–8683. *singhs@nidcd.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–662 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biomedical Library and Informatics Review Committee.

Date: March 9–10, 2006.

Time: March 9, 2006, 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, Second Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Time: March 10, 2006, 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, Second Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Arthur A. Petrosian, PhD, Scientific Review Administrator, Division of Extramural Programs, National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968. 301–496–4253. *petrosia@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–654 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel. High-End NMR Shared Instrumentation Grant Applications.

Date: February 3, 2006.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Clarion Hotel Bethesda Park, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sergei Ruvinov, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892. 301–435–1180. *ruvinser@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group. Medical Imaging Study Section.

Date: February 9–10, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Eileen W. Bradley, DSC, Scientific Review Administrator and Chief, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5100, MSC 7854, Bethesda, MD 20892. (301) 435–1179. *bradleye@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group. Biobehavioral Regulation, Learning and Ethology Study Section.

Date: February 9–10, 2006.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Luci Roberts, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3188, MSC 7848, Bethesda, MD 20892. 301–435–0692. *roberlu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Surgery, Anesthesia, and Trauma Member Conflict.
Date: February 10, 2006.
Time: 2:30 p.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).
Contact Person: Roberto J. Matus, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892. 301–435–22204. *matusr@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group. Skeletal Biology Development and Disease Study Section.
Date: February 12–14, 2006.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Wyndham City Center Hotel, 1143 New Hampshire Ave., NW., Washington, DC 20037.
Contact Person: Priscilla B. Chen, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892. 301–435–1787. *chenp@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group. Biology and Diseases of the Posterior Eye.
Date: February 13–14, 2006.
Time: 8 a.m. to 5:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Michael H. Chaitin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7850, Bethesda, MD 20892. (301) 435–0910. *chaitinm@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group. Moter Function, Speech and Rehabilitation Study Section.
Date: February 13–14, 2006.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Georgetown Suite, 1000 29th Street, NW., Washington, DC 20007.
Contact Person: Biao Tian, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3089B, MSC 7848, Bethesda, MD 20892. 301–402–4411. *tianbi@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Targeting Disease Caused by Protein Misfolding or Misprocessing.
Date: February 13–14, 2006.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.
Contact Person: Zhenya Li, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1113, MSC 7849, Bethesda, MD 20892. (301) 435–2417. *lizhenya@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Neurodegeneration, Neuroinflammation, Oxidative Stress and Mitochondria.
Date: February 13–14, 2006.
Time: 8 a.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.
Contact Person: Carole L. Jelsema, PhD, Chief and Scientific Review Administrator, MDCN Scientific Review Group, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7850, Bethesda, MD 20892. 301–435–1248. *jelsemac@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Bridges to the Future.
Date: February 13, 2006.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: The River Inn, 924 25th Street, NW., Washington, DC 20037.
Contact Person: Cathleen L. Cooper, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4208, MSC 7812, Bethesda, MD 20892. 301–435–3566. *cooperc@csr.nih.gov.*

Name of Committee: Digestive Sciences Integrated Review Group. Hepatobiliary Pathophysiology Study Section.
Date: February 13–14, 2006.
Time: 8 a.m. to 6:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Rass M. Shayiq, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892. 301–435–2359. *shaylqr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Computational Biophysics.
Date: February 13, 2006.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.
Contact Person: George W. Chacko, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4186, MSC 7849, Bethesda, MD 20892. 301–435–1220. *chackoge@csr.nih.gov.*

Name of Committee: Oncological Sciences Integrated Review Group. Drug Discovery and Molecular Pharmacology Study Section.
Date: February 13–14, 2006.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Wyndham Washington, DC, 1400 M Street, NW., Washington, DC 20005.
Contact Person: Morris I. Kelsey, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892. 301–435–1718. *kelseym@csr.nih.gov.*

Name of Committee: Oncological Sciences Integrated Review Group. Cancer Genetics Study Section.
Data: February 13–14, 2006.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.
Contact Person: Zhiqiang Zou, PhD, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, MSC 7804, Bethesda, MD 20892. 301–451–0132. *zouzhiq@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Member Conflicts in Depression, Bipolar Disorder and Social Phobia.
Date: February 13, 2006.
Time: 10 a.m. to 12 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).
Contact Person: Dana Jeffrey Plude, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7848, Bethesda, MD 20892. 301–435–2309. *pluded@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Skeletal Muscle Biology and Exercise Physiology: A Member Conflict Panel.
Date: February 14, 2006.
Time: 11:30 a.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).
Contact Person: Tamizchelvi Thyagarajan, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016K, MSC 7814, Bethesda, MD 20892. 301–451–1327. *tthyagar@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group. Surgery, Anesthesiology and Trauma Study Section.
Date: February 15–16, 2006.
Time: 1 p.m. to 2 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.
Contact Person: Weihua Luo, PhD, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892. 301–435–1170. *luow@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Member SEP in Cell Biology.

Date: February 15, 2006.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Alexandra M. Ainsztein, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7840, Bethesda, MD 20892. 301–451–3848. *ainsztea@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Gene Therapy and Inborn Errors.

Date: February 15–16, 2006.

Time: 5 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC, 20037.

Contact Person: Richard Panniers, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892. 301–435–1741. *pannierr@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group. Cellular Aspects of Diabetes and Obesity Study Section.

Date: February 15–17, 2006.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 740 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ann A. Jerkins, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6154, MSC 7892, Bethesda, MD 20892. 301–435–4514. *jerkinsa@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.893, National Institutes of Health, HHS)

Dated: January 13, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–641 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Software Development and Maintenance.

Date: January 17–18, 2006.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue, NW., Washington, DC 20036.

Contact Person: Zhenya Li, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1113, MSC 7849, Bethesda, MD 20892, (301) 435–2417, *lizhenya@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Neuroimmune Mechanisms and Chronic Fatigue Syndrome.

Date: January 26, 2006.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Executive Plaza North, 6130 Executive Blvd., Conference Rooms C & D, Rockville, MD 20852.

Contact Person: J. Terrell Hoffeld, PhD, DDS, Dental Officer, USPHS, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7816, Bethesda, MD 20892, 301–435–1781, *th88q@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Oncological Sciences Integrated Review Group Cancer Molecular Pathobiology Study Section.

Date: January 29–31, 2006.

Time: 6 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

Contact Person: Elaine Sierra-Rivera, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Biomedical Computing and Health Informatics.

Date: February 1–2, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20891, (Virtual Meeting).

Contact Person: Bill Bunnag, PhD, Scientific Review Administration, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5124, MSC 7854, Bethesda, MD 20892, (301) 435–1177, *bunnagb@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group Integrative and Clinical Endocrinology and Reproduction Study Section.

Date: February 2–3, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Abubakar A. Shaikh, DVM, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6168, MSC 7892, Bethesda, MD 20892, (301) 435–1042, *shaikha@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Oncological Sciences Integrated Review Group Tumor Progression and Metastasis Study Section.

Date: February 2–3, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Martin L. Padarathsingh, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6212, MSC 7804, Bethesda, MD 20892, (301) 435–1717, *padaratm@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflicts: Visual Processes ZRG1 IFCNA (03).

Date: February 3, 2006.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Christine L. Melchior, PhD, Scientific Review Administrator, Center

for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, 301–435–1713, *melchioc@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.878, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.892, 93.893, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–646 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussion could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel. Intercellular Interactions.

Date: February 2–3, 2006.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Raya Mandler, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217, MSC 7840, Bethesda, MD 20892. (301) 402–8228. *rayam@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group. Membrane Biology and Protein Processing.

Date: February 2–3, 2006.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Marcia Steinberg, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5130, MSC 7840, Bethesda, MD 20892. (301) 435–1023. *steinbem@csr.nih.gov.*

Name of Committee: Digestive Sciences Integrated Review Group. Clinical and Integrative Gastrointestinal Pathobiology Study Section.

Date: February 6–7, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mushtaq A. Khan, DVM, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2176, MSC 7818, Bethesda, MD 20892. 301–435–1778. *khanm@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group. Bioengineering, Technology and Surgical Sciences Study Section.

Date: February 6–7, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Dharam S. Dhindsa, DVM, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5110, MSC 7854, Bethesda, MD 20892. (301) 435–1174. *dhindsad@csr.nih.gov..*

Name of Committee: Digestive Sciences Integrated Review Group. Gastrointestinal Cell and Molecular Biology Study Section.

Date: February 6–7, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Najma Begum, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2175, MSC 7818, Bethesda, MD 20892. 301–435–1243. *begumn@csr.nih.gov..*

Name of Committee: Oncological Sciences Integrated Review Group.

Date: February 6–7, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Bo Hong, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892. 301–435–5879. *hongb@csr.nih.gov..*

Name of Committee: Regulatory Sciences Integrated Review Group. Lung Injury, Repair, and Remodeling Study Section.

Date: February 6–7, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ghenima Dirami, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2159, MSC 7818, Bethesda, MD 20892. 301–435–1321. *diramig@csr.nih.gov..*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Chemistry/Biophysics Program Project.

Date: February 6, 2006.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Vonda K. Smith, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4172, MSC 7806, Bethesda, MD 20892. 301–435–1789. *smithvo@csr.nih.gov..*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group.

Date: February 7–8, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael A. Steinmetz, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5172, MSC 7844. Bethesda, MD 20892. 301–435–1247. *steinmem@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group. Biochemistry and Biophysics of Membranes Study Section.

Date: February 7–8, 2006.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

Contact Person: Nuria E. Assa-Munt, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3120, MSC 7806, Bethesda, MD 20892. (301) 451–1323. *assamunu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Antimicrobial Agents Drug Discovery.

Date: February 7, 2006.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Fouad A. El-Zaatari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20814–9692. (301) 435–1149. *elzaataf@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Fetal Alcohol Exposure.

Date: February 7, 2006.
Time: 1 p.m. to 2:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).
Contact Person: Christine L. Melchior, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892. 301–435–1713. *melchioc@csr.nih.gov.*

Name of Committee: Digestive Sciences Integrated Review Group. Xenobiotic and Nutrient Disposition and Action Study Section.
Date: February 8–9, 2006.
Time: 8 a.m. to 1 p.m.
Agenda: To review and evaluate grant applications.
Place: Wyndham City Center Hotel, 1143 New Hampshire Ave., NW., Washington, DC 20037.
Contact Person: Patricia Greenwel, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2174, MSC 7818, Bethesda, MD 20892. 301–435–1169. *greenwep@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group. Synthetic and Biological Chemistry A Study Section.
Date: February 8–9, 2006.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.
Contact Person: Robert Lees, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4182, MSC 7806, Bethesda, MD 20892. (301) 435–2684. *leesro@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Oral Microbiology and Signal Transduction: A Member Conflict Panel.
Date: February 8, 2006.
Time: 12:30 p.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).
Contact Person: Tamizchelvi Thyagarajan, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016K, MSC 7814, Bethesda, MD 20892. 301–451–1327. *tthyagar@csr.nih.gov..*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group. Biomedical Imaging Technology Study Section.
Date: February 9–10, 2006.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 02109.
Contact Person: Lee Rosen, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892. 301–435–1171. *rosenl@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group. Pathogenic Eukaryotes Study Section.
Date: February 9–10, 2006.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.
Contact Person: Jean Hickman, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3194, MSC 7808, Bethesda, MD 20892. 301–435–1146. *hickmanj@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group. Cell Structure and Function.
Date: February 9–10, 2006.
Time: 8 a.m. to 5:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Baltimore on the Inner Harbor, 300 Light Street, Baltimore, MD 21202.
Contact Person: Alexandra M. Ainsztein, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5144, MSC 7840, Bethesda, MD 20892. 301–451–3848. *ainsztea@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group. Neurobiology of Motivated Behavior Study Section.
Date: February 9–10, 2006.
Time: 8 p.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Gamil C. Debbas, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7844, Bethesda, MD 20892. (301) 435–1018. *debbasg@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group. Synapses, Cytoskeleton and Trafficking Study Section.
Date: February 9–10, 2006.
Time: 8 a.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.
Contact Person: Jonathan K. Ivins, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040A, MSC 7806, Bethesda, MD 20892. (301) 594–1245. *ivinsj@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group. Macromolecular Structure and Function A Study Section.
Date: February 9–10, 2006.
Time: 8 a.m. to 3:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.
Contact Person: Janet Nelson, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892. (301) 435–1723. *nelsonja@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group. Neuroendocrinology, Neuroimmunology, and Behavior Study Section.
Date: February 9–10, 2006.
Time: 8 a.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Michael Selmanoff, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3134, MSC 7844, Bethesda, MD 20892. (301) 435–1119. *mselmanoff@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group. Neurotransporters, Receptors, and Calcium Signaling Study Section.
Date: February 9–10, 2006.
Time: 8 a.m. to 5:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue, NW., Washington, DC 20036.
Contact Person: Peter B. Guthrie, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892. (301) 435–1239. *guthriep@csr.nih.gov.*

Name of Committee: Health of the Population Integrated Review Group. Community Influences on Health Behavior.
Date: February 9–10, 2006.
Time: 8:30 a.m. to 3 p.m.
Agenda: To review and evaluate grant applications.
Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.
Contact Person: Ellen K. Schwartz, EDD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3168, MSC 7770, Bethesda, MD 20892, (301) 435–0681, *schwarte@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Infectious Disease, Reproductive Health, Asthma, and Pulmonary Epidemiology.
Date: February 9–10, 2006.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA 22202.
Contact Person: Sandra L. Melnick, DRPH, Scientific Review Administrator, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 3028D, MSC 7770, Bethesda, MD 20892, (301) 435–1251, *melnicks@csr.nih.gov.*

Name of Committee: Biology of Development and Aging Integrated Review Group, International and Cooperative Projects—1 Study Section.

Date: February 9, 2006.

Time: 9 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Zakir Bengali, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, MSC 7842, Bethesda, MD 20892, (301) 435–1116, *bengaliz@csr.nih.gov.*

Name of Committee: Health of the Population Integrated Review Group, Community-Level Health Promotion Study Section.

Date: February 9–10, 2006.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications

Place: Hotel Helix, 1430 Rhode Island Avenue, NW., Washington, DC 20005.

Contact Person: William N. Elwood, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3162, MSC 7770, Bethesda, MD 20892, (301) 435–1503, *elwoodwi@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, GRIP Review.

Date: February 9–10, 2006.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Zakir Bengali, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, MSC 7842, Bethesda, MD 20892, (301) 435–1116, *bengaliz@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Bioengineering Research Partnerships.

Date: February 10, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Xiang-Ning Li, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, (301) 435–1744, *lixiang@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 11, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–647 Filed 1–23–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[DHS–2005–0056]

Privacy Impact Assessment

AGENCY: Department of Homeland Security, United States Visitor and Immigrant Status Indicator Technology Program.

ACTION: Notice of availability of Privacy Impact Assessment.

SUMMARY: The Department of Homeland Security intends to modify the United States Visitor and Immigrant Status Indicator Technology Program to conduct the second phase of a live test of the technology required to read biometrically enabled travel documents that comply with international standards. As a result, US–VISIT is revising its Privacy Impact Assessment to discuss the impact of Phase II of the live test on privacy. This revised Privacy Impact Assessment is available on the Web site of the Privacy Office of the Department of Homeland Security, *http://www.dhs.gov/privacy*, and on the US–VISIT Web site, *http://www.dhs.gov/usvisit.* It is also available by written request to US–VISIT.

ADDRESSES: You may submit comments on the revised Privacy Impact Assessment, identified by Docket Number DHS–2005–0056, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Fax: (202) 298–5201 (not a toll-free number).
- E-mail: *usvisitprivacy@dhs.gov.*
- Mail: Steve Yonkers, Privacy Officer, US–VISIT, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Steve Yonkers, Privacy Officer, US–VISIT, Department of Homeland Security, Washington, DC 20528, by telephone (202) 298–5200 or facsimile (202) 298–5201; Maureen Cooney, Acting Chief Privacy Officer, Department of Homeland Security, Arlington, VA 22202 by telephone (571) 227–3813 or facsimile (571) 227–4171.

SUPPLEMENTARY INFORMATION: On June 16, 2005, the United States Visitor and Immigrant Status Indicator Technology (US–VISIT) Program announced its intention to conduct a live test of the technology required to read biometrically enabled travel documents that comply with international standards. In connection with Phase I of that test, US–VISIT published a revised version of its Privacy Impact Assessment (PIA) addressing the privacy concerns associated with the live test. (70 FR 35110).

US–VISIT is now set to begin Phase II of the live test, which will operate from January 15, 2006, until April 15, 2006. During Phase II, basic access controls of e-Passports will be tested against the selected U.S. document reader solution at one U.S. port of entry and on international airport. Because the implementation of Phase II modifies the privacy risk associated with the US–VISIT Program, the Department of publishing another update to its PIA.

The revised Privacy Impact Assessment is available on the Web site of the Privacy Office of the Department of Homeland Security, *http://www.dhs.gov/privacy,* and on the US–VISIT Web site, *http://www.dhs.gov/usvisit.* It is also available by written request to US–VISIT at the address provided above.

Dated: January 6, 2005.

Maureen Cooney,

Acting Chief Privacy Officer, Department of Homeland Security.

[FR Doc. E6–766 Filed 1–23–06; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–21093]

Notification of the Imposition of Conditions of Entry for Certain Vessels Arriving to the United States

AGENCY: Coast Guard, DHS.

ACTION: Notice of policy.

SUMMARY: The Coast Guard announces that effective anti-terrorism measures

are not in place in certain ports of Equatorial Guinea and that it will impose conditions of entry on vessels arriving from that country. The Coast Guard also announces that conditions of entry are being removed from vessels arriving from ports in the Democratic Republic of Congo.

DATES: The policy announced in this notice is effective on February 7, 2006.

ADDRESSES: The Docket Management Facility maintains the public docket for this notice. This notice will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket, including this notice, on the Internet at *http://dms.dot.gov.*.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call Mr. Mike Brown, Coast Guard, telephone 202–267–4330.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Section 70110 of the Maritime Transportation Security Act provides that the Secretary of Homeland Security may impose conditions of entry into the United States from ports that are not maintaining effective anti-terrorism measures. The Coast Guard has been delegated the authority by the Secretary to carry out the provisions of this section. The Docket contains previous notices imposing or removing conditions of entry on vessels arriving from certain countries and those conditions of entry and the countries they pertain to remain in effect unless modified by this notice.

The Coast Guard has determined that ports, with certain exceptions, in Equatorial Guinea are not maintaining effective anti-terrorism measures. Accordingly, effective February 7, 2006, the Coast Guard will impose the following conditions of entry on vessels that visited ports in Equatorial Guinea with the exception of Punta Europa, K–5, Luba, Zafiro, and Ceiba during their last five port calls. Vessels must:

- Implement measures per the ship's security plan equivalent to Security Level 2;
- Ensure that each access point to the ship is guarded and that the guards have total visibility of the exterior (both landside and waterside) of the vessel while the vessel is in ports in the above countries. Guards may be provided by the ship's crew, however additional crewmembers should be placed on the ship if necessary to ensure that limits on maximum hours of work are not exceeded and/or minimum hours of rest are met, or provided by outside security forces approved by the ship's master and Company Security Officer;
- Attempt to execute a Declaration of Security;
- Log all security actions in the ship's log;
- Report actions taken to the cognizant U.S. Coast Guard Captain of the Port prior to arrival into U.S. waters; and
- Ensure that each access point to the ship is guarded by armed, private security guards and that they have total visibility of the exterior (both landside and waterside) of the vessel while in U.S. ports. The number and position of the guards has to be acceptable to the Coast Guard Captain of the Port.

Based on recent information, the Coast Guard is removing the conditions of entry announced in its previously published Notice of Policy (70 FR 22668) for the Democratic Republic of Congo.

With this notice, the current list of countries not maintaining effective anti-terrorism measures is as follows: Equatorial Guinea, Guinea-Bissau, Liberia, and Mauritania.

January 10, 2006.

Craig E. Bone,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Prevention, Acting.

[FR Doc. E6–756 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–23652]

Temporary Authorization To Extend Certificates of Inspection and Certificates of Compliance

AGENCY: Coast Guard, DHS.

ACTION: Notice of policy.

SUMMARY: The Coast Guard announces that Congress authorized (through H.R. 4508), the Secretary of Homeland Security to extend temporarily the duration or the validity of Certificates of Inspection and Certificates of Compliance that are issued under chapter 33 or 37, respectively, of title 46, U.S. Code. These certificates may be extended for up to three (3) months for any vessel inspected by the Coast Guard in Alabama, Mississippi, or Louisiana.

DATES: This temporary extension authorization for the Secretary of Homeland Security expires on February 28, 2006.

ADDRESSES: Vessel owners or operators must send written requests for extensions to the local Officer in Charge, Marine Inspection (OCMI) for consideration.

FOR FURTHER INFORMATION CONTACT: If you have questions regarding this notice, contact Lieutenant Commander Brian J. Downey, Office of Vessel Activities (G–PCV–1), by telephone 202–267–0495, fax 202–267–4394, or e-mail *BDowney@comdt.uscg.mil*. If you have questions on viewing to the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202–493–0402.

SUPPLEMENTARY INFORMATION:

Background

Following the devastation of Hurricane Katrina that struck the U.S. Gulf Coast on August 29, 2005, the Coast Guard mounted an unprecedented emergency response. Urgent reprioritization of Coast Guard missions and reallocation of resources was required to effectively manage the regional response. In an effort to reduce the impact to the marine industry because of the Coast Guard's hurricane response measures, Congress authorized temporary vessel inspection regulatory relief through H.R. 4508.

Policy

Vessel owners or operators must send written requests for extensions to the local Officer in Charge, Marine Inspection (OCMI) for consideration. OCMIs, at their discretion, may extend expiration dates for Certificates of Inspection (COIs) and Certificates of Compliance (COCs) that will expire before February 28, 2006. Extensions are only authorized in cases where the OCMI lacks resources to provide timely service or in cases where vessel operators clearly document that an extension is required to provide direct/emergent hurricane relief efforts. Vessels, not normally inspected in Alabama, Mississippi or Louisiana are not eligible for extension. Vessels with certificates expiring after February 28, 2006 are not eligible for extension. Vessel owner/operator requests should define the length of extension required (not to exceed 90 days), outline the cause for the extension, and should attest to the vessel's substantial compliance with applicable inspection regulations. OCMIs must authorize all extensions with official correspondence to the requester detailing the extended expiration date. Vessels operating with expired COIs and COCs without a written extension are in violation of

applicable vessel inspection laws and can be subject to enforcement action.

Dated: January 13, 2006.

Craig E. Bone,

Rear Admiral, U.S. Coast Guard, Acting Assistant Commandant for Prevention.

[FR Doc. E6–754 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Automated Commercial Environment (ACE): National Customs Automation Program Test of Automated Truck Manifest for Truck Carrier Accounts; Deployment Schedule

AGENCY: Customs and Border Protection; Department of Homeland Security.

ACTION: General notice.

SUMMARY: The Bureau of Customs and Border Protection, in conjunction with the Department of Transportation, Federal Motor Carrier Safety Administration, is currently conducting a National Customs Automation Program (NCAP) test concerning the transmission of automated truck manifest data. This document announces the next two groups, or clusters, of ports to be deployed for this test.

DATES: *Effective Dates:* The ports identified in this notice, in the state of Texas, are expected to deploy in two clusters no earlier than January 2006, as provided in this notice. Comments concerning this notice and all aspects of the announced test may be submitted at any time during the test period.

FOR FURTHER INFORMATION CONTACT: Mr. James Swanson via e-mail at *James.Swanson@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The National Customs Automation Program (NCAP) test concerning the transmission of automated truck manifest data for truck carrier accounts was announced in a General Notice published in the **Federal Register** (69 FR 55167) on September 13, 2004. That notice stated that the test of the Automated Truck Manifest would be conducted in a phased approach, with primary deployment scheduled for no earlier than November 29, 2004. The document identified the ports of Blaine, Washington, and Buffalo, New York, as the original deployment sites.

The September 13, 2004, notice stated that subsequent deployment of the test would occur at Champlain, New York; Detroit, Michigan; Laredo, Texas; Otay Mesa, California; and Port Huron, Michigan, on dates to be announced. The notice stated that the Bureau of Customs and Border Protection (CBP) would announce the implementation and sequencing of truck manifest functionality at these ports as they occur and further stated that additional participants and ports would be selected throughout the duration of the test. The test is to be expanded eventually to include ACE Truck Carrier Account participants at all land border ports, and subsequent releases of ACE will include all modes of transportation.

Implementation of the Test

The test commenced in Blaine, Washington in December 2004, but not at Buffalo, New York. In light of experience with the implementation of the test in Blaine, Washington, CBP decided to change the implementation schedule and published a General Notice in the **Federal Register** on May 31, 2005 (70 FR 30964) announcing the changes.

As noted in the May 31, 2005, General Notice, the next deployment sites will be brought up as clusters. In some instances, one site in the cluster will be identified as the ''model site'' or ''model port'' for the cluster. This deployment strategy will allow for more efficient equipment set-up, site checkouts, port briefings and central training.

The ports identified belonging to the first cluster announced in the May 31, 2005, notice included the original port of implementation: Blaine, Washington. Sumas, Washington, was designated as the model port. The other ports of deployment in the cluster included the following: Point Roberts, WA; Oroville, WA (including sub ports); Boundary, WA; Danville, WA; Ferry, WA; Frontier, WA; Laurier, WA; Metaline Falls, WA; Nighthawk, WA; and Lynden, WA.

In a notice published in the **Federal Register** (70 FR 43892) on July 29, 2005, CBP announced that the test was being further deployed, in two clusters, at ports in the States of Arizona and North Dakota. CBP stated that the test would be deployed at the following ports in Arizona as of July 25, 2005: Douglas, AZ; Naco, AZ; Lukeville, AZ; Sasabe, AZ; and Nogales, AZ. Douglas, AZ was designated as the model port. The test was also to be deployed, according to information provided in the notice, at the following ports in North Dakota as of August 15, 2005: Pembina, ND; Neche, ND; Noyes, ND; Walhalla, ND; Maida, ND; Hannah, ND; Sarles, ND; and Hansboro, ND. Pembina, ND, was designated as the model port.

In a General Notice published in the **Federal Register** (70 FR 60096) on October 14, 2005, CBP announced that the test was to be further deployed in a cluster of ports, in the State of Michigan, no earlier than the dates indicated as follows (all in the year 2005): Windsor Tunnel, October 4; Barge Transport, October 5; Ambassador Bridge, October 7; Port Huron, October 14; Marine City, October 18; Algonac, October 18; and Sault St. Marie, October 28. No port in this cluster was designated as a ''model port.''

New Clusters

Through this notice, CBP announces the next two clusters of ports to be brought up for purposes of implementation of the test. The test will be deployed at the following cluster of ports no earlier than January 2006: Eagle Pass, Texas and Del Rio, Texas. The test will also be deployed no earlier than January 2006 at the following cluster of ports: Brownsville, Texas; Pharr, Texas; Progresso, Texas; Rio Grande City, Texas; and Roma, Texas. No ports in these clusters are designated as ''model ports.''

Previous NCAP Notices Not Concerning Deployment Schedules

On Monday, March 21, 2005, a General Notice was published in the **Federal Register** (70 FR 13514) announcing a modification to the NCAP test to clarify that all relevant data elements are required to be submitted in the automated truck manifest submission. That notice did not announce any change to the deployment schedule and is not affected by publication of this notice. All requirements and aspects of the test, as set forth in the September 13, 2004 notice, as modified by the March 21, 2005 notice, continue to be applicable.

Dated: January 12, 2006.

William S. Heffelfinger III,

Acting Assistant Commissioner, Office of Field Operations.

[FR Doc. 06–620 Filed 1–23–06; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review; Monthly

Report Naturalization Papers; Form N–4. OMB Control No. 1615–0051.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on November 22, 2005, at 70 FR 70631. The notice allowed for a 60-day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 23, 2006. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Director, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov*. When submitting comments by e-mail please make sure to add OMB Control Number 1615–0051 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Monthly Report Naturalization Papers.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N–4; U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Federal, State or local Governments. Section 339 of the Immigration and Nationality Act (Act) requires that the clerk of each court that administers the oath of allegiance notify the U.S. Citizenship and Immigration Services (USCIS) of all persons to whom the oath of allegiance for naturalization is administered, within 30 days after the close of the month in which the oath was administered. This form provides a format for submitting a list of those persons to USCIS and provides accountability for the delivery of the certificates of naturalization as required under that section of law.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 160 respondents at 12 responses annually at 30 minutes (.50) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 960 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please visit the USCIS Web site at: *http://uscis.gov/graphics/formsfee/forms/pra/index.htm*.

If additional information is required contact: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, 3rd Floor, Washington, DC 20529, (202) 272–8377.

Dated: January 17, 2006.

Richard A. Sloan,

Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 06–560 Filed 1–23–06; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review; USCIS Case Status Service Online; OMB Control Number 1615–0080.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on November 22, 2005, at 70 FR 70631. The notice allowed for a 60-day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 23, 2006. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Director, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov*. When submitting comments by e-mail please make sure to add OMB Control Number 1615–0080 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* USCIS Case Status Service Online.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* No Agency Form No. (File No. OMB–33). U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This system allows individuals or their representatives to request case status of their pending application through USCIS' Web site.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 24,000,000 respondents at 2¾ minutes (.046) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,104,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please visit the USCIS Web site at: *http://uscis.gov/graphics/formsfee/forms/pra/index.htm*.

If additional information is required contact: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, 3rd Floor, Washington, DC 20529, (202) 272–8377.

Dated: January 17, 2006.

Richard A. Sloan,

Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 06–561 Filed 1–23–06; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5044–N–01]

Notice of Proposed Information Collection for Public Comment—Lease Requirements, Recordkeeping

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 27, 2006.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control number and should be sent to: Aneita Waites, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4116, Washington, DC 20410–5000.

FOR FURTHER INFORMATION CONTACT: Aneita Waites, (202) 708–0713, extension 4114. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) 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; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

This Notice also lists the following information:

Title of Proposal: Lease Requirements—24 CFR 966.4, Recordkeeping.

OMB Control Number: 2577–0006.

Description of the need for the information and proposed use: The collection of information is contained in HUD regulations at 24 CFR 966.4. Public Housing Agencies (PHAs) are required to keep records for implementation of Federal regulations governing dwelling leases in public housing. The information is retained by the PHAs that manage public housing and is used for operating purposes.

Agency form numbers, if applicable: None.

Members of affected public: State or Local Government; individuals or households.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: 3,330 responses, one time for new and modified leases, 48 average hours per response, 158,400 hours total recordkeeping burden.

Status of the proposed information collection: Reinstatement, without change.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: January 18, 2006.

Bessy Kong,

Deputy Assistant Secretary, Office of Policy, Program and Legislative Initiative.

[FR Doc. E6–817 Filed 1–23–06; 8:45 am]

BILLING CODE 4210–33–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR 5044–N–02]

Notice of Proposed Information Collection for Public Comment Screening and Eviction for Drug Abuse and Other Criminal Activity

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: March 27, 2006.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB Control number and should be sent to: Aneita Waites, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4116, Washington, DC 20410–5000.

FOR FURTHER INFORMATION CONTACT: Aneita L. Waites, (202) 708–0713, extension 4114, for copies of the proposed forms and other available

documents (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) 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; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

This Notice also lists the following information:

Title of Proposal: Screening and Eviction for Drug Abuse and Other Criminal Activity—Final Rule.

OMB Control Number: 2577–0232.

Description of the need for the information and proposed use: The collection of information implements statute and gives Public Housing Agencies (PHAs) and assisted housing owners the tools for adopting and implementing fair, effective and comprehensive policies for screening out program applicants who engage in illegal drug use or other criminal activity and for evicting or terminating assistance of persons who engage in such activity. PHAs that administer a Section 8 or public housing program under an Annual Contributions Contract (ACC) with HUD may request criminal history records from any law enforcement agency concerning an adult member of a household applying for admission to a public housing or Section 8 program.

Agency form numbers, if applicable: None.

Members of affected public: State or Local Government; Public Housing Agencies (PHAs).

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: 3,300 PHAs (respondents); estimated average number of respondents 15,200; total annual burden hours 73,550.

Status of the proposed information collection: Extension.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: January 18, 2006.

Bessy Kong,

Deputy Assistant Secretary, Office of Policy, Program and Legislative Initiatives.

[FR Doc. E6–819 Filed 1–23–06; 8:45 am]

BILLING CODE 4210–33–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Choctaw National Wildlife Refuge

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of Availability of the Draft Comprehensive Conservation Plan and Environmental Assessment for Choctaw National Wildlife Refuge in Choctaw County, Alabama.

SUMMARY: The Fish and Wildlife Service announces that a Draft Comprehensive Conservation Plan and Environmental Assessment for Choctaw National Wildlife Refuge are available for review and comment. The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, requires the Service to develop a comprehensive conservation plan for each national wildlife refuge. The purpose in developing a comprehensive conservation plan is to provide refuge manages with a 15-year strategy for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and Service policies, In addition to outlining broad management direction on conserving wildlife and their habitats, plans identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation.

Significant issues addressed in the draft plan include: threatened and endangered species, waterfowl management, neotropical migratory birds, bottomland hardwood restoration, fisheries management, visitor services, funding and staffing, cultural resources, and land protection.

DATES: A meeting will be held to present the plan to the public. Mailings, newspaper articles, and posters will be the avenues to inform the public of the date and time for the meeting. Individuals wishing to comment on the Draft Comprehensive Conservation Plan and Environmental Assessment for Choctaw National Wildlife Refuge should do so no later than March 10, 2006.

ADDRESSES: Requests for copies of the Draft Comprehensive Conservation Plan and Environmental Assessment should be addressed to Choctaw National Wildlife Refuge, P.O. Box 808, Jackson, Alabama 36545; Telephone 251/246–3583. The plan and environmental assessment may also be accessed and downloaded from the Service's Internet Web site *http://southeast.fws.gov/planning/*. Comments on the draft plan may be submitted to the above address or via electronic mail to *mike_dawson@fws.gov*. Please include your name and return address in your Internet message. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home addresses from the record, which we will honor to the extent allowed by law.

SUPPLEMENTARY INFORMATION: The Service developed four alternatives for managing the refuge and chose Alternative D as the preferred alternative.

Alternatives

The draft comprehensive conservation plan and environmental assessment evaluates the four alternatives for managing the refuge over the next 15 years. These alternatives are briefly described as follows:

Alternative A: No Action (Current Management Direction)

Choctaw National Wildlife Refuge's most important terrestrial vegetation community is its bottomland hardwood forests, which provide habitat for migratory birds, including both waterfowl and neotropical migratory forest-dependent birds, and other species. The refuge has a current Forest Management Plan, but it has not been fully implemented; some stand treatments have been applied, but secondary treatments, such as thinnings, have not. Regeneration is occurring on the forest floor, but not stand recruitment; saplings are not maturing due to being eaten by deer and feral hogs, frequent flooding, and shady conditions. There is a dense canopy at present that inhibits regeneration of all but the most shade-tolerant trees. While

mast production is a good at present, it will probably decrease over the long term as oaks become over-mature and are not replaced by younger, more vigorous and productive oaks.

Backwaters, sloughs, and wetlands on the refuge are gradually filling in with sediments, a natural process of ecological succession that has been accelerated by human activity, namely the Coffeeville Dam and Reservoir standing water, in which sediments drop out and accumulate. This long-term process will continue under the Current Management Direction Alternative.

The main aquatic invasive species on the refuge at present are hydrilla, alligator weed, and water hyacinth; the potential exists for additional species to become problematic, as is giant salvinia. Major infestation by aquatic invasives of virtually all water bodies at present are displacing native aquatic/wetland plants and can exacerbate siltation. This, in turn, degrades fish habitat, including raising water temperature and reducing dissolved oxygen. There are also significant effects on water-based recreation and waterfowl habitat. At present, 75 acres of backwater slough emergents per year are treated with herbicides and this will continue under this alternative. To a lesser extent, biological controls will also continue to be used.

Invasive terrestrial plants and animals on the refuge include cogongrass and feral hogs. Cogongrass is sprayed annually. Feral hogs are in incidental species, which can be taken during other refuge hunts. The staff conducts limited trapping of these animals on the refuge. A recent reduction in the refuge's population of feral hogs appears to be due to off-refuge trapping by one or more neighboring landowners. Under the Current Management Direction Alternative, there will continue to be limited trapping and incidental hunting of feral hogs on the refuge.

As mentioned above, the refuge's bottomland hardwood forests provide important habitat for waterfowl and neotropical migratory birds, as well as resident wildlife. In addition, the refuge actively manages habitat for migratory birds by means of force-account farming (35 acres) and moist-soil management (15 acres at present). Under the Current Management Direction Alternative, these acreages will not change. The refuge also assists in the reproduction of the wood duck by providing 400 nest boxes; these are cleaned once annually. Staff members monitor them and collect nesting data.

Two federally listed species—the bald eagle and the wood stork—are documented as occurring on the refuge. Two active bald eagle nests are located on the refuge; these are protected by sanctuaries that involve some restriction of public access by boaters, anglers, hunters, and other refuge users. Wood storks are observed occasionally during the summer. This is a population that nests in Florida and migrates north after the nesting season.

With regard to resource protection, the Corps of Engineers has limited funds for dredging areas of the refuge that have been filling in with sediments. The Service's Daphne, Alabama, Ecological Services Office has contaminants specialists who, in the past, have conducted contaminants surveys but these are now dated and no complete surveys have ever been conducted. Oil and gas rights on the refuge are outstanding, and production necessitates communication and cooperation with oil/gas companies to reduce above-ground impacts and disturbance, as well as to avoid, minimize, and mitigate spills and contamination.

The principal public use on the refuge is fishing, which is regulated by the State of Alabama. Both bank fishing and boat fishing are available. Concerns have been expressed by the public about declining quality of the fishing experience, mainly because of degraded aquatic habitat from invasives and reduced access to potential fishing areas that have been rendered impenetrable due to emergent weedy vegetation. The Alabama Division of Wildlife and Freshwater Fisheries conducts periodic creel and angler surveys.

Secondary public uses on the refuge are hunting and wildlife observation. There is one wildlife observation platform, next to the moist-soil units. There is a 0.5-mile loop interpretive trail near the platform. Other forest roads permit foot travel, but access is difficult (only by boat). Current refuge hunts include an archery hunt for deer, and a small game season for squirrels, rabbits, and raccoons. There is no waterfowl hunting. The same public access and use under this alternative would continue; to gain access to many areas is by boat only from the reservoir.

The staff works with private land owners of approximately eight Farm Service Agency tracts to restore bottomland hardwood forests (*i.e.*, planting oak trees) on easement areas.

Isolation of the refuge itself from the refuge headquarters—45 minutes to 1 hour away by road—inhibits hands-on refuge management; for example, there is no law enforcement, biological, forestry, or management presence on the refuge half of the time. The refuge itself is remote, and frequent flooding makes much of it inaccessible for much of year. This isolation and seasonal inaccessibility will continue under the Current Management Direction Alternative.

The current number of staff at the refuge is four: The refuge manager and an office assistant are located at the headquarters in Jackson, Alabama, and two maintenance workers are located on the refuge itself. As a result of staffing and budgetary limitations, there are limited data on wildlife and habitat distributions and trends, which inhibits the quantification of management objectives.

Alternative B. Enhanced Wildlife/ Fisheries and Habitat Management

Under Alternative B, the refuge would update and fully implement its Forest Management Plan. Some tree harvest removal would be necessary to achieve understory and midstory conditions, with an emphasis on regeneration of bottomland hardwood oaks and other mast-bearing trees. As feasible, the Service would work with the Corps of Engineers to help adjust hydrological periods so that summer flooding occurs at fewer intervals and for shorter periods. The reason is to not kill oak trees and stymie oak regeneration.

With regard to backwaters, sloughs, and wetlands filling in with sediments, this alternative would use aerial and GPS/GIS techniques to document current colonization by plants and sedimentation trends over time. Aquatic invasive species would be kept under control via cooperative agreements with the Corps of Engineers and the State of Alabama. The refuge would initiate discussions with the Corps to reduce impacts of too-frequent inundation by the Coffeeville Dam and Reservoir and with the State to utilize approved methods of controlling invasive aquatic plants, which help trap sediments and worsen the problem. The result would be more effective control and reduced severity of infestations and slower sedimentation of refuge waters.

Cogongrass would be sprayed annually with the objective being to eradicate this exotic invasive species. The refuge would investigate replacing cogongrass on one bank it now infests, which provides ground cover to avoid erosion, with a native plant species. Programs like the State Landowner Incentive Program may offer funding or technical support that could be used in private lands habitat and wildlife management, including control of problem species, such as feral hogs. Partners for Fish and Wildlife is another

program that might offer support to the refuge.

Alternative B would provide habitat for migratory birds, including waterfowl and neotropical, by using force-account farming (*e.g.,* millet and grain sorghum) and intensified moist-soil management. Staff would level and regrade moist-soil units to facilitate water management; in addition, the area of moist soil would be increased to 25–35 acres by converting existing crop fields. Over the 15-year life of the plan, all crop fields would be phased out and transitioned to moist-soil units.

Under this alternative, staff would maintain the existing stock of 400 wood duck nest boxes, but more intensively monitor and collect nesting data from them. Each nest box would be cleaned at least twice annually, from once annually at present.

Two active bald eagle nests are on the refuge and would remain active under Alternative B. They would continue to be protected by sanctuaries that involve some restriction of public access by boaters, anglers, hunters, and other refuge visitors. It is assumed that wood storks would continue to be observed occasionally during the summer, as in the Current Management Direction Alternative. Under the Enhanced Wildlife/Fisheries and Habitat Management Alternative, the Service would investigate the movements of these wood storks via a radio telemetry study.

The refuge would obtain the assistance of contaminants specialists at the Service's Daphne, Alabama, Ecological Services Office to conduct contaminants surveys on the refuge to update information on key toxic contaminants, such as mercury and other heavy metals, pesticides, and salt water. Oil and gas production on the refuge would continue under Alternative B, necessitating communication and cooperation with oil companies to reduce above-ground impacts and disturbance, as well as to avoid, minimize, and mitigate spills and contamination.

The principal wildlife-dependent recreation under the Enhanced Wildlife/Fisheries and Habitat Management Alternative would continue to be fishing, regulated by the State of Alabama. Both bank and boat fishing would be available. The State would conduct periodic creel and angler surveys, as it does at present. Improved aquatic habitat management would aim to increase fish populations and angler access. This alternative would explore stump removal to improve both fisheries habitat and boat access.

Secondary public uses would continue to be hunting and wildlife observation. There would be one wildlife observation platform, next to the moist-soil units, as at present, and a 0.5-mile loop interpretive trail near the platform. Other forest roads would permit foot travel, but overall access would remain difficult (only by boat). Under Alternative B, the Service would look to build a bridge across the mouth of Okatuppa Creek to facilitate management access; this bridge would also be accessible to public foot travel. Refuge hunts would include those held currently: an archery hunt for deer, and a small game season for squirrels, rabbits, and raccoons. No waterfowl hunting would be permitted. Feral hogs would be considered incidental species and could be taken during all refuge hunts. The same public access and use under this alternative would continue; to gain access to many areas would remain only by boat from the reservoir.

The staff would continue to monitor habitat restoration of approximately eight Farm Service Agency tracts planted in bottomland hardwood forests.

Under the Enhanced Wildlife/Fisheries and Habitat Management Alternative, isolation of the refuge itself from refuge headquarters would continue to inhibit hands-on management. The remoteness of the refuge would not change, and frequent flooding would continue to render much of it inaccessible for much of the year.

One assistant refuge manager with law enforcement collateral duty would be added, as well as one wildlife biologist. The refuge would investigate sharing a forester with other refuges. Recommended staffing would consist of a refuge manager, assistant refuge manager, and office assistant at the refuge headquarters, and a biologist and two maintenance workers on the refuge itself.

Alternative C. Enhanced Wildlife-Dependent Recreation

Under Alternative C, the refuge's existing Forest Management Plan, which has not been fully implemented, would continue in effect, but again would not be fully implemented. Some stand treatments would be applied, but secondary treatments (thinnings) would not. Regeneration would occur on the forest floor, but stand recruitment would continue to lag. Most saplings would not mature because of heavy foraging pressure by white-tailed deer and feral hogs, frequent flooding, and shady conditions. A dense canopy would continue to inhibit regeneration of all but the most shade-tolerant trees. At first, mast production would remain high, but would probably decrease over the long term (*i.e.,* beyond the 15-year life of the comprehensive conservation plan) as oaks become over-mature and are not replaced by younger, more vigorous and productive oaks.

Backwaters, sloughs, and wetlands on the refuge would continue gradually filling in with sediments, a natural process of ecological succession that has been accelerated by human activity, namely the Coffeeville Dam and Reservoir's standing water, in which sediments drop out and accumulate. This long-term process would continue under the Enhanced Wildlife-Dependent Recreation Alternative.

Although the main aquatic invasive species on the refuge are hydrilla, alligator weed, and water hyacinth at present, the potential exists for additional species to become problematic, such as giant salvinia. Major infestation by aquatic invasives of virtually all waterbodies at present are displacing native aquatic/wetland plants like giant bulrush and can exacerbate siltation. This, in turn, degrades fish habitat, including raiding water temperature and reducing dissolved oxygen. There are also significant effects on water-based recreation and waterfowl habitat. At present, 75 acres of backwater slough emergents per year are treated with herbicides and this would continue under this alternative. To a lesser extent, biological controls would also continue to be used.

There would be no change in the management of invasive terrestrial plants and animals on the refuge under this alternative from the Current Management Direction Alternative.

The refuge would continue to actively manage habitat for migratory birds by means of force-account farming and moist-soil management. Under this alternative, the acreages would not change from the acreages being farmed under the Current Management Direction Alternative.

The refuge would continue to assist in the reproduction of the wood duck by providing 400 nest boxes and managing as is currently being done.

Management of two federally listed species—bald eagle and wood stork—would remain the same as under the Current Management Direction Alternative.

With regard to resource protection, the Corps of Engineers has limited funds for dredging areas of the refuge that have been filling in with sediments. The Service's Daphne, Alabama, Ecological Services Office has contaminants

specialists who, in the past, have conducted contaminants surveys but these are now dated and no complete surveys have ever been conducted. Oil and gas rights on the refuge are outstanding, and production necessitates communication and cooperation with oil/gas companies to reduce above-ground impacts and disturbance, as well as to avoid, minimize, and mitigate spills and contamination.

Refuge staff would continue to work with private landowners on approximately eight Farm Service tracts to restore bottomland hardwood forests on easement areas.

Under Alternative C, the principal wildlife-dependent recreation would remain fishing, regulated by the State. Both bank and boat fishing would be available. The State would continue to conduct periodic creel and angler surveys. Within five years of the comprehensive conservation plan's approval, the refuge would build new fishing facilities, such as a handicapped accessible fishing pier. It would also provide additional woody structure within the reservoir, and open boating access via stump removal and increased aquatic vegetation control.

Secondary public uses would continue to be hunting and wildlife observation in the Enhanced Wildlife-Dependent Recreation Alternative. This alternative would also offer an improved wildlife observation platform, next to the moist-soil units. The Service would seek to build a pedestrian bridge over the mouth of Okatuppa Creek to facilitate and improve access to Middle Swamp. Refuge hunts would include an archery hunt for deer, and small game season for squirrels, rabbits, and raccoons. A waterfowl hunt for youths would be added, contingent upon having staffing resources to manage the hunt. Feral hogs would be considered an incidental species and could be taken during all refuge hunts. The same public access and use would continue under this alternative; to gain access to many areas would remain by boat only from the reservoir. More environmental education opportunities both on and off the refuge would be pursued.

Isolation of the refuge from its headquarters would continue to inhibit hands-on management. Alternative C would add one assistant refuge manager with law enforcement collateral duty, as well as one park ranger. Recommended staffing would then be six: Refuge manager, assistant refuge manager, and office assistant at refuge headquarters, and a park ranger and two maintenance workers on the refuge.

Alternative D. Enhanced Wildlife/ Fisheries, Habitat, and Public Use (Preferred Alternative)

Under Alternative D, the refuge would update and fully implement its Forest Management Plan. Some tree harvest removal would be necessary to achieve understory and midstory conditions, with an emphasis on regeneration of bottomland hardwood oaks and other mast-bearing trees. As feasible, the Service would work with the Corps of Engineers to adjust hydrological periods so that summer flooding occurs at fewer intervals and for shorter periods. This would avoid oak seedling mortality that now thwarts oak regeneration.

With regard to the refuge backwaters, sloughs, and wetlands now filling in with sediments, Alternative D would utilize aerial and GPS/GIS techniques to document current colonization by plants and sedimentation trends over time. Aquatic invasive species would be kept under control via cooperative agreements with the Corps of Engineers and the State of Alabama. The refuge would initiate discussions with the Corps to reduce impacts of too-frequent inundation by the Coffeeville Dam and Reservoir, and with the State to utilize approved methods of controlling invasive aquatic plants, which help trap sediments and worsen the problem. The result would be more effective control and reduced severity of infestations and slower sedimentation of refuge waters.

Cogongrass would be sprayed annually with the objective being to eradicate this exotic invasive species. The refuge would investigate replacing cogongrass on one bank it now infests, which provides ground cover to avoid erosion, with a native plant species. Programs like the State Landowner Incentive Program may offer funding or technical support that could be used in private lands habitat and wildlife management, including control of problem species like feral hogs. Another possibility that the refuge would explore using is the Partners for Fish and Wildlife program.

Alternative D would provide habitat for migratory birds, including waterfowl and neotropical migratory birds, by using force-account farming (e.g., millet and grain sorghum) and intensified moist-soil management. Staff would level and regrade moist-soil units to facilitate water management; in addition, the area of moist soil would be increased to 25–35 acres by converting existing crop fields. Over the 15-year life of the comprehensive conservation plan, all crop fields would be phased out and transitioned to moist-soil units.

Under this alternative, staff would maintain the existing stock of 400 wood duck nest boxes, but more intensively monitor and collect nesting data from them. Each nest box would be cleaned at least twice annually (from once annually at present).

Two active bald eagle nests are on the refuge and would remain active under Alternative D. They would continue to be protected by sanctuaries that involve some restriction of public access by boaters, anglers, hunters and other refuge visitors. It is assumed that wood storks would continue to be observed occasionally during the summer, as in the Current Management Direction Alternative. Under Alternative D, the Service would investigate the movements of these wood storks via a radio telemetry study.

Under the preferred alternative only, the refuge would request the assistance of contaminants specialists form the Service's Daphane, Alabama, Ecological Services Office to conduct complete contaminants surveys on the refuge to update information on the status of key toxic contaminants, such as mercury and other heavy metals, pesticides, and salt water. Oil and gas production on the refuge would continue, necessitating communication and cooperation with oil companies to reduce above-ground impacts and disturbance, as well as to avoid, minimize, and mitigate spills and contamination.

Under Alternative D, the principal wildlife-dependent recreation would remain fishing, regulated by the State of Alabama. Both bank and boat fishing would be available. The State would continue to conduct periodic creel and angler surveys. Within 5 years of approval of the comprehensive conservation plan, the refuge would build new fishing facilities, such as a handicapped accessible fishing pier. It would also provide additional woody structure within the reservoir, and open boating access via stump removal and increased aquatic vegetation control.

Secondary public uses would continue to be hunting and wildlife observation as in the Enhanced Wildlife-Dependent Recreation Alternative. This alternative would also offer an improved wildlife observation platform, next to the moist-soil units. The Service would seek to build a pedestrian bridge over the mouth of Okatuppa Creek to facilitate and improve access to Middle Swamp. Refuge hunts would include an archery hunt for deer, and a small game season for squirrels, rabbits and raccoons. A waterfowl hunt for youths would be added, contingent on having staffing resources to manage the hunt. The same

public access and use under this alternative would continue; to gain access to many areas would remain by boat only from the reservoir. Many more environmental education opportunities both on and off the refuge would be pursued.

Even under Alternative D, isolation of the refuge from its headquarters would continue to hamper hands-on refuge management. The alternative would add one assistant refuge manager with law enforcement collateral duty, and one wildlife biologist with visitor services collateral duty; and would also investigate sharing a forester with other refuges. Recommended staffing would be six: Refuge manager, assistant refuge manager, and office assistant at refuge headquarters, and a biologist and two maintenance workers on the refuge.

Authority: This notice is published under the authority of the National Wildlife Refuge System Improvement Act of 1997, Public Law 105–57.

Dated: July 25, 2005.

Linda H. Kelsey,

Acting Regional Director.

[FR Doc. 06–616 Filed 1–23–06; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Proposed Programmatic Statewide Red-cockaded Woodpecker Safe Harbor Agreement, Florida

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of permit application.

SUMMARY: The Florida Fish and Wildlife Conservation Commission (FFWC or Applicant) has applied to the Fish and Wildlife Service (Service) for an enhancement of survival permit (ESP) pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*). The ESP application includes a proposed Safe Harbor Agreement (Agreement) for the endangered red-cockaded woodpecker, (*Picoides borealis*) (RCW), for a period of 99 years. If approved, the Agreement would allow the Applicant to issue Certificates of Inclusion (CI) throughout the State of Florida to eligible non-Federal landowners that complete an approved Safe Harbor Management Agreement (SHMA).

We announce the opening of a 30-day comment period and request comments from the public on the Applicant's ESP application; the accompanying proposed Agreement, and the supporting Environmental Action Statement (EAS) Screening Form. All comments received, including names and addresses, will become part of the official administrative record and may be made available to the public, subject to the requirements of the Privacy Act and Freedom of Information Act. For further information and instructions on reviewing and commenting on this application, see the **ADDRESSES** section, below.

DATES: Written comments should be received on or before February 23, 2006.

ADDRESSES: You may obtain a copy of the information available by contacting the Service's Regional Safe Harbor Coordinator, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345, or Field Supervisor, U.S. Fish and Wildlife Service, Ecological Services Field Office, 1601 Balboa Avenue, Panama City, Florida 32405. Alternatively, you may set up an appointment to view these documents at either location during normal business hours. Written data or comments should be submitted to the Atlanta, Georgia, Regional Office. Requests for the documentation must be in writing to be processed, and comments must be in writing to be considered. When you are requesting or reviewing the information provided in this notice, please reference ''Proposed Programmatic Statewide Red-cockaded Woodpecker Safe Harbor Agreement, Florida'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Gooch, Regional Safe Harbor Program Coordinator at the Service's Southeast Regional Office (see **ADDRESSES** above), telephone (404) 679–7124; or Mr. Stan Simpkins, Ecologist, Panama City Ecological Services Field Office (see **ADDRESSES** above), telephone (850) 769–0552.

SUPPLEMENTARY INFORMATION: Primary threats to the RCW throughout its range all have the same basic cause: lack of suitable habitat. To help address this threat, the Service has previously entered into programmatic Safe Harbor Agreements in Georgia, Louisiana, and South Carolina. These previous agreements are similar to the Agreement that is being proposed by FFWC.

Under a Safe Harbor Agreement, participating property owners voluntarily undertake management activities on their property to enhance, restore, or maintain habitat benefiting species listed under the Act. Safe Harbor Agreements encourage private and other non-Federal property owners to implement conservation efforts for listed species by assuring property owners they will not be subjected to increased property use restrictions if their efforts attract listed species to their property or increase the numbers or distribution of listed species already on their property. Application requirements and issuance criteria for ESPs through Safe Harbor Agreements are found in 50 CFR 17.22 and 17.32.

The FFWCs proposed state-wide Agreement is designed to encourage voluntary RCW habitat restoration or enhancement activities by relieving a landowner who enters into a landowner-specific agreement (the SHMA) from any additional responsibility under the Act beyond that which exists at the time he or she enters into the program. The SHMA will identify any existing RCWs and any associated habitat (the baseline) and will describe the actions that the landowner commits to take (*e.g.*, hardwood midstory removal, cavity provisioning, prescribed burning, etc.) or will allow to be taken to improve RCW habitat on the property, and the time period within which those actions are to be taken and maintained. A participating landowner must maintain the baseline on his/her property (*i.e.*, any existing RCW groups and/or associated habitat), but may be allowed the opportunity to incidentally take RCWs at some point in the future if above baseline RCWs are attracted to that site by the proactive management measures undertaken by the landowner. It is important to note that the Agreement does not envision, nor will it authorize, incidental take of any pre-SHMA existing RCW group with one exception. This exception is incidental take related to a baseline shift; in this circumstance the baseline will be maintained but redrawn or shifted on that landowner's property. Among the minimization measures proposed by the Applicant are no incidental take of RCWs during the breeding season, consolidation of small, isolated RCW populations at sites capable of supporting a viable RCW population, and measures to improve current and potential habitat for the species. Further details on the topics described above are found in the aforementioned documents available for review under this notice.

The geographic scope of the Applicant's Agreement is the entire State of Florida, but the Agreement would only authorize the future incidental take of above-baseline RCW groups on lands for which a CI has been issued. Lands potentially eligible for inclusion include all privately owned lands and public lands owned by cities, counties, and municipalities, with potentially suitable RCW habitat in Florida.

The agreement is expected to attract sufficient interest among Florida landowners to generate substantial conservation benefits to the RCW on a landscape scale. FFWCs agreement was developed in an adaptive management framework to allow changes in the program based on new scientific information including, but not limited to, biological needs and management actions proven to benefit the species or its habitat.

We have made a preliminary determination that issuance of the ESP will not result in significant environmental, economic, social, historical, cultural impacts and is therefore, categorically excluded from review under the National Environmental Policy Act (NEPA) of 1969, as amended pursuant to 516 Department Manual 2, Appendix 1 and 516 Department Manual 6 Appendix 1. In addition, we have evaluated the proposed ESP under section 106 of the National Historic Preservation Act and have concluded that this Agreement will not affect cultural resources on or eligible for, the National Historic Register of Historic Places. We base our conclusions on our review of the process for protection and consideration of cultural resources included in the associated Agreement as well as the scope of the voluntary management actions identified in the Agreement. We have consulted with the Florida State Historic Preservation Officer and have received concurrence with our conclusion. We have also consulted with the appropriate Tribal Preservation Officers.

We provide this notice pursuant to section 10(c) of the Act and pursuant to implementing regulations for NEPA (40 CFR 1506.6). We will evaluate the proposed Agreement, associated documents, and comments submitted thereon to determine whether the requirements of section 10(a) of the Act and NEPA have been met. If we determine that the requirements are met, we will issue an ESP under section 10(a)(1)(A) of the Act to the Applicant in accordance with the terms of the Agreement and specific terms and conditions of the authorizing ESP. We will not make our final decision until after the end of the 30-day comment period and will fully consider all comments received during the comment period.

Dated: December 28, 2005.

Cynthia K. Dohner,

Acting Regional Director.

[FR Doc. E6–797 Filed 1–23–06; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Proposed Information Collection Under the Paperwork Reduction Act; Comment Request

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Indian Affairs (BIA) invites comments on two information collection requests which will be renewed. The two collections are: Class III Gaming Procedures, 1076–0149, and Tribal Revenue Allocation Plans, 1076–0150.

DATES: Submit your comments and suggestions on or before March 27, 2006, to be assured of consideration.

ADDRESSES: Comments should be sent to: George Skibine, Bureau of Indian Affairs, Office of Indian Gaming Management, Mail Stop 4600–MIB, 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Interested persons may get copies of the information collection requests without charge by contacting George Skibine at (202) 219–4066 or facsimile number (202) 273–3153.

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 provides an opportunity for interested parties to comment on proposed information collection requests. The Bureau of Indian Affairs, Office of Indian Gaming Management is proceeding with this public comment period as the first step in getting a normal information collection clearance from the Office of Management and Budget (OMB). Each request contains (1) type of review, (2) title, (3) summary of the collection, (4) respondents, (5) frequency of collection, (6) reporting and recordkeeping requirements.

Please note that we will not sponsor nor conduct, and you need not respond to, a request for information unless we display the OMB control number and the expiration date.

Class III Gaming Procedures

Type of review: Renewal.

Title: Class III Gaming Procedures, 25 CFR 291.

Summary: The collection of information will ensure that the provisions of IGRA, the relevant provisions of State laws, Federal law and the trust obligations of the United States are met when federally recognized tribes submit Class III procedures for review and approval by the Secretary of the Interior. Sections 291.4, 291.10, 291.12 and 291.15 of 25 CFR Part 291, Class III Gaming Procedures, specifies the information collection requirement. An Indian tribe must ask the Secretary to issue Class III gaming procedures. The information to be collected includes: The name of Tribe and the State, tribal documents, State documents, regulatory schemes, the proposed procedures and other documents deemed necessary. Collection of this information is currently authorized under an approval by OMB (OMB Control Number 1076–0149). All information is collected when the tribe makes a request for Class III gaming procedures. Annual reporting and recordkeeping burden for this collection of information is estimated to occur one time on an annual basis. The estimated number of annual requests is 12 tribes seeking Class III gaming procedures. The estimated time to review instructions and complete each application is 320 hours. Thus, the total annual reporting and recordkeeping burden for this collection is estimated to be 3,840 hours.

Frequency of Collection: Annually.

Description of Respondents: Federally recognized tribes.

Total Respondents: 12.

Burden Hours per Application: 320.

Total Annual Burden Hours: 3,840 hours.

Tribal Revenue Allocation Plans

Type of review: Extension of a currently-approved collection.

Title: Tribal Revenue Allocation Plans, 25 CFR 290.

Summary: In order for Indian tribes to distribute net gaming revenues in the form of per capita payments, information is needed by the BIA to ensure that Tribal Revenue Allocation Plans include assurances that certain statutory requirements are met, a breakdown of the specific uses to which net gaming revenues will be allocated, eligibility requirements for participation, tax liability notification and the assurance of the protection and preservation of the per capita share of minors and legal incompetents. Sections 290.12, 290.17, 290.24 and 290.26 of 25 CFR Part 290, Tribal Revenue Allocation Plans, specifies the information collection requirement. An Indian tribe must ask the Secretary to approve a Tribal Revenue Allocation Plan. The information to be collected includes: name of Tribe, tribal documents, the allocation plan and other documents deemed necessary. Collection of this information is currently authorized under an approval by OMB (OMB

Control Number 1076–0152). All information is collected when the Tribe submits a Tribal Revenue Allocation Plan. Annual reporting and record keeping burden for this collection of information is estimated to average between 75–100 hours for approximately 50 respondents, including the time for reviewing instructions, researching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Thus, the total annual reporting and recordkeeping burden for this collection is estimated to be 3,750—5,000 hours. We are using the higher estimate for purposes of estimating the public burden.

Frequency of Collection: Annually.

Description of Respondents: Federally recognized tribes.

Total Respondents: 50.

Burden Hours per Response: 100.

Total Annual Burden Hours: 5,000 hours.

Request for Comments

The Bureau of Indian Affairs solicits comments in order to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the bureau, including whether the information will have practical utility;

(2) Evaluate the bureau's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility and clarity of the information to be collected; and

(4) Minimize the burden of the collection of the information on those who are to respond.

Any public comments received will be addressed in the Bureau of Indian Affairs' submission of the information collect request to the Office of Management and Budget.

All comments will be available for public review during regular business hours. There may be an instance when we decide to withhold information, but if you wish us to withhold your name and address, you must state this prominently at the beginning of your comment. We will honor your request to the extent allowed by law. We will not consider anonymous comments, and we will make public all comments from businesses and from individuals who represent businesses.

Dated: January 12, 2006.

Michael D. Olsen,

Acting Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. E6–816 Filed 1–23–06; 8:45 am]

BILLING CODE 4310–4N–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–040–06–1610–DP]

Notice of Extension of the Public Comment Period for the Ring of Fire Draft Resource Management Plan/Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Extension of the Public Comment Period for the Ring of Fire Draft Resource Management Plan/Environmental Impact Statement.

SUMMARY: The Bureau of Land Management (BLM) announces an extension of the public comment period on the Ring of Fire Draft Resource Management Plan/Environmental Impact Statement (RMP/EIS). The original notice issued September 30, 2005, provided for a comment period to end on December 29, 2005. BLM is extending the comment period until January 30, 2006.

DATES: Written comments on issues relating to the future land use, planning, and management of the Ring of Fire Planning Area must be submitted or postmarked no later than January 30, 2006.

ADDRESSES: Comments on the document should be addressed to Robert Lloyd, Project Manager, Ring of Fire RMP/EIS, Bureau of Land Management, Anchorage Field Office (040), 6881 Abbott Loop Road, Anchorage, Alaska 99507. Comments can also be submitted by accessing the e-mail box developed for this project at *akrofrmp@blm.gov.*

FOR FURTHER INFORMATION CONTACT: Robert Lloyd, (907) 267–1214, or by mail at the Anchorage Field Office, 6881 Abbott Loop Road, Anchorage, Alaska 99507.

SUPPLEMENTARY INFORMATION: The original Notice of Availability was published September 30, 2006, and provided for comments on the Ring of Fire Draft RMP/EIS to be received through December 29, 2005. During the public comment period it was discovered that the maps depicting the proposed Neacola Mountains Area of Critical Environmental Concern contained errors. Trustees for Alaska requested an extension of the comment period in order to further review the recommendation. BLM has decided to act in accordance with this request, therefore, comments on the Ring of Fire Draft RMP/EIS will now be accepted through January 30, 2006.

Dated: January 6, 2006.

Henri R. Bisson,

State Director.

[FR Doc. E6–774 Filed 1–23–06; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

National Park Service

Route 66 Corridor Preservation Program, Advisory Council; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act, Public Law 92–463, that a meeting of the Route 66 Corridor Preservation Program Advisory Council will be held February 9 and 10, 2006, at the Hotel Albuquerque at Old Town, 800 Rio Grande, NW., Albuquerque, New Mexico. The meeting will begin at 8:30 a.m. on February 9 and will end by 1 p.m. on February 10.

The Route 66 Corridor Preservation Program Advisory Council was established to consult with the Secretary of the Interior on matters relating to the Route 66 Corridor Preservation Program, including recommendations for ways to best preserve important properties along Route 66, recommendations for grant and cost-share awards to eligible applicants owning or administering historic properties along the Route 66 Corridor, and recommendations for technical assistance provided by the National Park Service to partners along the route.

The matters to be discussed include:

—Assessment/general recommendations of program to date
— assessment/recommendations for cost-share grants
— assessment/recommendations for technical assistance (site visits, workshops, community meetings, etc.)

The meeting will be open to the public. However, facilities and space for accommodating members of the public are limited, and persons will be accommodated on a first-come, first-served basis. Any member of the public may file a written statement concerning the matters to be discussed with Michael Taylor, Route 66 Corridor Preservation Program Manager.

Persons wishing further information concerning this meeting, or who wish to submit written statements may contact

Michael Taylor, Route 66 Corridor Preservation Program Manager, National Trails System—Santa Fe, National Park Service, P.O. Box 728, Santa Fe, New Mexico 87504–0728, telephone 505/988–6742. Minutes of the meeting will be available for public inspection at the Route 66 Corridor Preservation Program Office, located in Room 122, Old Santa Fe Trail Building, 1100 Old Santa Fe Trail, Santa Fe, New Mexico.

Dated: January 17, 2006.

Bernard C. Fagan,

Deputy Chief, Office of Policy.

[FR Doc. E6–760 Filed 1–23–06; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

San Luis Unit Long-Term Contract Renewal

AGENCY: Bureau of Reclamation, Interior.

ACTION: Second extension of comment period for review of Draft Environmental Impact Statement (DEIS).

SUMMARY: The Bureau of Reclamation (Reclamation) is extending the comment period for the DEIS to April 3, 2006. The notice of availability of the DEIS was published in the **Federal Register** on September 30, 2005 (70 FR 57324). The public comment period was originally to end on November 21, 2005. A notice to extend the comment period to January 17, 2006 was published in the **Federal Register** on December 6, 2005 (70 FR 72652).

DATES: Submit comments on the DEIS on or before April 3, 2006.

ADDRESSES: Send comments on the DEIS to Mr. Shane Hunt, Bureau of Reclamation, South-Central California Area Office, 1243 N Street, Fresno, CA 93721. Comments may also be e-mailed to *shunt@mp.usbr.gov*. Copies of the DEIS may be requested by calling Mr. Hunt at 559–487–5138, TDD 559–487–5933.

FOR FURTHER INFORMATION CONTACT: Mr. Shane Hunt at 559–487–5138, TDD 559–487–5933.

SUPPLEMENTARY INFORMATION: This extension will allow Reclamation to prepare and release supplemental information as part of the review process for this action. Reclamation decided to prepare this supplemental information to address issues and concerns that have been identified following preparation of the DEIS. The supplemental information will be available February 2006, at least 45 days before the end of the comment period on the DEIS. The public and agencies will be able to review this information concurrently with the DEIS released October 7, 2005, and may provide comments on the DEIS and the supplemental information in a single response. The final environmental impact statement will consider and contain responses to all substantive comments received on the DEIS.

Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold a respondent's identity from public disclosure, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public disclosure in their entirety.

Dated: January 3, 2006.

Frank Michny,

Regional Environmental Officer, Mid-Pacific Region.

[FR Doc. E6–796 Filed 1–23–06; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF JUSTICE

Office of Community Oriented Policing Services (COPS); Agency Information Collection Activities: Extension of Currently Approved Collection; Comments Requested

ACTION: 30-Day Notice of Information Collection Under Review: Methamphetamine Project Status Update Report (SUR).

The Department of Justice (DOJ) Office of Community Oriented Policing Services (COPS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 70, Number 209, on page 62330 on October 31, 2005, allowing for a 60-day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until February 23, 2006. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Methamphetamine Project Status Update Report (SUR).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: None. U.S. Department of Justice Office of Community Oriented Policing Services (COPS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Law Enforcement Agencies and government entities that are Methamphetamine grant recipients. Other: Universities and Private Non-Profit Agencies. Abstract: The

information collected will be used by the COPS Office to determine grantee's progress toward grant implementation and for compliance monitoring efforts.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There will be an estimated 100 responses from methamphetamine grantees. The estimated amount of time required for the average respondent to respond is 3 hours and 15 minutes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total burden associated with the collection is 325 hours.

If additional information is required contact: Brenda Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: January 18, 2006.

Brenda Dyer,

Department Clearance Officer, United States Department of Justice.

[FR Doc. E6–787 Filed 1–23–06; 8:45 am]

BILLING CODE 4410–AT–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under Comprehensive Environmental Response, Compensation and Liability Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on January 10, 2006, a proposed Consent Decree in *United States* v. *Beehive Barrel and Drum, Inc. d/b/a Cascade Cooperage, Inc.* (D. Utah), C.A. No. 2:04–CV–00570 (TC), was lodged with the United States District Court for the District of Utah, Central Division.

In this action, the United States seeks response costs incurred and to be incurred by the Environmental Protection Agency (''EPA''), pursuant to Section 107 of the Comprehensive Environmental Response, Compensation and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9607, in connection with the Service First Barrel and Drum Site, located in Salt Lake City, Utah. Three defendants, Adria Rossomondo, Arthur Rossomondo, and Beehive Barrel and Drum, Inc. d/b/a Cascade Cooperage, Inc. (''Rossomondo Defendants''), have resolved the United States' response cost claims through this Consent Decree. The settlement incorporated in the Consent Decree does not resolve the United States' response cost claims or any other claim with respect to the five other defendants named in the complaint.

The Consent Decree provides, *inter alia*, that the Rossomondo Defendants and EPA will enter into a settlement pursuant to EPA's ability-to-pay policies and procedures. As part of settlement negotiations, EPA requested that the Rossomondo Defendants provide information regarding each defendant's financial status, and the Rossomondo Defendants cooperatively provided all of the requested information, which was necessary under EPA's policies and procedures to perform an ability-to-pay settlement analysis. Based upon the analysis, EPA determined that the Rossomondo Defendants had the financial ability to pay a nominal amount, or $325.00, of EPA's response costs that were incurred in connection with the clean-up of the Site.

The Department of Justice will receive, for a period of 30 days from the date of this publication, comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Beehive Barrel and Drum, Inc. d/b/a Cascade Cooperage, Inc.,* DOJ Ref. No. 90–11–3–08170.

The proposed Consent Decree may be examined at the Office of the United States Attorney, 185 South State, Ste. 400, Salt Lake City, Utah 84111; and U.S. EPA Region 8, 999 18th Street, Denver, Colorado 80202. During the public comment period, the proposed Consent Decree may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/open.html.* A copy of the proposed Consent Decree may be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood *(tonia.fleetwood@usdoj.gov)*, fax number (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy of the Consent Decree from the Consent Decree Library, please enclose a check in the amount of $6.00 (.25 cents per page reproduction costs), payable to the U.S. Treasury.

Robert D. Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 06–603 Filed 1–23–06; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended, (19 U.S.C. 2273), the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the periods of January 2006.

In order for an affirmative determination to be made and a certification of eligibility to apply for directly-impacted (primary) worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act,

African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance as an adversely affected secondary group to be issued, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of (a) (2) (A) (increased imports) of Section 222 have been met.

TA–W–58,327; Hewlett Packard, Ontario, CA, November 10, 2004.

TA–W–58,412; F. Schumacher and Company, Newark Customer Service Facility, Newark, DE, November 28, 2004.

TA–W–58,526; IPF Management Company, Inc., d/b/a Invincible IPF, Paterson, NJ, December 20, 2004.

TA–W–58,070; Carrier Access Corporation, Boulder, CO, October 4, 2004.

TA–W–58,326; Reliable Garment, Los Angeles, CA, November 10, 2004.

TA–W–58,401; Accutech Mold and Engineering, Little Falls, MN, November 22, 2004.

TA–W–58,456; WestPoint Home, Inc., Bath Products Div., Ambassador Personnel, Valley, AL, December 2, 2004.

TA–W–57,987; Sun Chemical, Performance Pigments Division, Cincinnati, OH, September 12, 2004.

TA–W–58,388; Chuan Hing Sewing, Inc., San Francisco, CA, November 21, 2004.

The following certifications have been issued. The requirements of (a)(2)(B) (shift in production) of Section 222 have been met.

TA–W–58,396; Leesburg Knit Mill, Knitting Div., Union Underwear Co., Inc., Leesburg, AL, November 21, 2004.

TA–W–58,480; LeSportsac, Inc., Stearns, KY, November 30, 2004.

TA–W–58,499; Metaldyne Corporation, LLC, Heartland Industrial Partners, Edon, OH, December 6, 2005.

TA–W–58,502; Wella Manufacturing of Virginia, USA Staffing, Spherion, STAT, Aerotek, Will Rogers, Richmond, VA, November 28, 2004.

TA–W–58,295; Pixelworks, Inc., Tualatin, OR, November 4, 2004.

TA–W–58,295A; Pixelworks, Inc., Campbell, CA, November 4, 2004.

The following certification has been issued. The requirement of supplier to a trade certified firm has been met.

None.

The following certification has been issued. The requirement of downstream producer to a trade certified firm has been met.

None.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

The investigation revealed that criterion (a)(2)(A)(I.A) and (a)(2)(B)(II.A) (no employment decline) has not been met.

TA–W–58,413; Badger Paper Mills, BPM, Inc., Flexible Packaging Div., Oconton Falls, WI.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B) (No shift in production to a foreign country) have not been met.

None.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B) (No shift in production to a foreign country) have not been met.

TA–W–58,421; Sony Electronics, Direct View CRT, Mt. Pleasant, PA.

TA–W–58,481; Collins and Aikman, Southwest Laminates, Inc. Division, El Paso, TX.

TA–W–58,274; Saint-Gobain Container, Carteret, NJ.

The investigation revealed that criteria (a)(2)(A)(I.C.) (Increased imports and (a)(2)(B)(II.C) (has shifted production to a foreign country) have not been met.

None.

The workers firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–58,487; U.S. Airways, Greentree Reservations, Pittsburgh, PA.

The investigation revealed that criteria (2) has not been met. The workers firm (or subdivision) is not a supplier or downstream producer to trade-affected companies.

None.

Affirmative Determinations for Alternative Trade Adjustment Assistance

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determinations.

In the following cases, it has been determined that the requirements of Section 246(a)(3)(ii) have been met.

I. Whether a significant number of workers in the workers' firm are 50 years of age or older.

II. Whether the workers in the workers' firm possess skills that are not easily transferable.

III. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

TA–W–58,396; Leesburg Knit Mill, Knitting Div., Union Underwear Co., Inc., Leesburg, AL, November 21, 2004.

TA–W–58,480; LeSportsac, Inc., Stearns, KY, November 30, 2004.

TA–W–58,499; Metaldyne Corporation, LLC, Heartland Industrial Partners, Edon, OH, December 6, 2005.

TA–W–58,502; Wella Manufacturing of Virginia, USA Staffing, Spherion,

STAT, Aerotek, Will Rogers, Richmond, VA, November 28, 2004.

TA–W–58,388; Chuan Hing Sewing, Inc., San Francisco, CA, November 21, 2004.

TA–W–58,456; WestPoint Home, Inc., Bath Products Div., Ambassador Personnel, Valley, AL, December 2, 2004.

TA–W–58,327; Hewlett Packard, Ontario, CA, November 10, 2004.

TA–W–58,526; IPF Management Company, Inc., d/b/a Invincible IPF, Paterson, NJ, December 20, 2004.

Negative Determinations for Alternative Trade Adjustment Assistance

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

In the following cases, it has been determined that the requirements of Section 246(a)(3)(ii) have not been met for the reasons specified.

Since the workers are denied eligibility to apply for TAA, the workers cannot be certified eligible for ATAA.

TA–W–58,487; U.S. Airways, Greentree Reservations, Pittsburgh, PA.

TA–W–58,274; Saint-Gobain Container, Carteret, NJ.

TA–W–58,421; Sony Electronics, Direct View CRT, Mt. Pleasant, PA.

TA–W–58,481; Collins and Aikman, Southwest Laminates, Inc. Division, El Paso, TX.

The Department as determined that criterion (1) of Section 246 has not been met. Workers at the firm are 50 years of age or older.

None.

The Department as determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

TA–W–58,295; Pixelworks, Inc., Tualatin, OR.

TA–W–58,295A; Pixelworks, Inc., Campbell, CA.

TA–W–58,070; Carrier Access Corporation, Boulder, CO.

TA–W–58,401; Accutech Mold and Engineering, Little Falls, MN.

TA–W–57,987; Sun Chemical, Performance Pigments Division, Cincinnati, OH.

The Department as determined that criterion (3) of Section 246 has not been met. Competition conditions within the workers' industry are not adverse.

None.

I hereby certify that the aforementioned determinations were issued during the month of January 2006. Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, during normal business hours or will be mailed to persons who write to the above address.

Dated: January 12, 2006.

Erica R. Cantor,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E6–803 Filed 1–23–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–58,309]

OBG Manufacturing Company; Liberty, KY; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at OBG Manufacturing Company, Liberty, Kentucky. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–58,309; OBG Manufacturing Company, Liberty, Kentucky (January 11, 2006).

Signed at Washington, DC this 11th day of January 2006.

Erica R. Cantor,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E6–802 Filed 1–23–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–58,047]

Plasti-Coil, Inc.; Lake Geneva, WI; Notice of Negative Determination Regarding Application for Reconsideration

By application of December 8, 2005 a petitioner requested administrative reconsideration of the Department's negative determination regarding eligibility for workers and former workers of the subject firm to apply for Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA). The denial notice was signed on November 10, 2005 and published in the **Federal Register** on December 6, 2005 (70 FR 72653).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The TAA petition, filed on behalf of workers at Plasti-Coil, Inc., Lake Geneva, Wisconsin engaged in production of custom injection molding was denied because the ''contributed importantly'' group eligibility requirement of Section 222 of the Trade Act of 1974 was not met, nor was there a shift in production from that firm to a foreign country. The ''contributed importantly'' test is generally demonstrated through a survey of the workers' firm's declining customers. The survey revealed no increase in imports of custom injection molding. The subject firm did not import custom injection molding in the relevant period, nor did it shift production to a foreign country.

In the request for reconsideration, the petitioner alleges that the layoffs at the subject firm are attributable to a shift in production to China. To support the allegations, the petitioner attached a copy of the letter from the subject firm's company official stating that ''a significant portion of the business has been transferred to China''.

A company official was contacted regarding the above allegations. The company official confirmed what was revealed during the initial investigation. In particular, the official stated that Plasti-Coil, Inc., Lake Geneva, Wisconsin was contemplating to move portion of its production to China, however, the shift did not occur and there are no current plans to move production from the subject firm to a foreign country. The official further clarified that the letter mentioned by the petitioner meant that the subject firm's customers transferred significant volumes of their business to China and other Asian countries, which had a negative impact on production of the

subject firm. The subject firm did not shift production of custom injection molding abroad.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC this 13th day of January, 2006.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–801 Filed 1–23–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–57,945; TA–W–57,945A]

Polyvision Corporation; 13646 Route 402 Highway North Facility; Clymer, PA; 2170 Barr Slope Road Facility; Dixonville, PA; Notice of Revised Determination on Reconsideration

By letter dated December 5, 2005, Greater Pennsylvania Regional Council of Carpenters requested administrative reconsideration regarding the Department's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to the workers of the subject firm.

The initial investigation resulted in a negative determination signed on October 21, 2005 and was based on the finding that imports of casework cabinets, marker and tack boards did not contribute importantly to worker separations at the subject plant and no shift of production to a foreign source occurred. The denial notice was published in the **Federal Register** on November 9, 2005 (70 FR 68099).

To support the request for reconsideration, the petitioner supplied additional information. The Department of Labor reviewed surveys of the firms to which the subject facility submitted bids and was not subsequently awarded the contracts. A further contact with the surveyed companies revealed the fact that all the bids were awarded to domestic bidders who manufacture case work cabinets, market boards and tack boards abroad. The loss of these contracts as a result of increased imports of case work cabinets, market boards and tack boards contributed importantly to the declines in sales and employment at the subject firm. The investigation further revealed that sales, production and employment at the subject firm declined during the relevant time period.

In accordance with Section 246 the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor herein presents the results of its investigation regarding certification of eligibility to apply for alternative trade adjustment assistance (ATAA) for older workers.

In order for the Department to issue a certification of eligibility to apply for ATAA, the group eligibility requirements of Section 246 of the Trade Act must be met. The Department has determined in this case that the requirements of Section 246 have been met.

A significant number of workers at the firm are age 50 or over and possess skills that are not easily transferable. Competitive conditions within the industry are adverse.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of articles like or directly competitive with those produced at Polyvision Corporation, Clymer, Pennsylvania (TA–W–57,945) and Polyvision Corporation, Dixonville, Pennsylvania (TA–W–57,945A), contributed importantly to the declines in sales or production and to the total or partial separation of workers at the subject firm. In accordance with the provisions of the Act, I make the following certification:

''All workers of Polyvision Corporation, Clymer, Pennsylvania (TA–W–57,945) and Polyvision Corporation, Dixonville, Pennsylvania (TA–W–57,945A) who became totally or partially separated from employment on or after September 8, 2004 through two years from the date of this certification, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.''

Signed in Washington, DC this 13th day of January 2006.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–800 Filed 1–23–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–57,838]

Texstyle, Inc., Manchester, KY; Notice of Affirmative Determination Regarding Application for Reconsideration

By application of October 17, 2005, petitioners requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to workers of TexStyle, Inc., Manchester, Kentucky (the subject firm). The negative determination for the subject firm was issued on September 15, 2005, and published in the **Federal Register** on October 31, 2005 (70 FR 62345).

Under a prior certification (TA–W–51,404), workers were eligible to apply for worker adjustment assistance (issued on April 21, 2003; expired on April 21, 2005). The investigation instituted on August 25, 2005, revealed that the workers did not produce an article or support an affiliated domestic production facility during the relevant period.

New information provided on December 1, 2005 by the subject firm revealed that some production did occur at TexStyle, Inc., Manchester, Kentucky during the relevant period.

The Department carefully reviewed the petitioners' request for reconsideration and has determined that the Department will conduct further investigation based on new information provided by the subject firm.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 22nd day of December 2005.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–799 Filed 1–23–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification

The petition for modification notice published in the **Federal Register** on

December 28, 2005 (70 FR 76892) for the R S & W Coal Company, Drift Mine, docket number M–2005–079–C, had the wrong MSHA I.D. Number. The correct MSHA I.D. Number is 36–01818.

The following parties have filed petitions to modify the application of existing safety standards under section 101(c) of the Federal Mine Safety and Health Act of 1977.

1. Anthracite Underground Rescue, Inc.

[Docket No. M–2005–085–C]

Anthracite Underground Rescue, Inc., 44 Crescent Street, Tremont, Pennsylvania 17981 has filed a petition to modify the application of 30 CFR 49.6(a)(1) & (5) (Equipment and maintenance requirements) for the following Anthracite Underground Mines in District 1: Alfred Brown Coal Company, 7 FT Slope Mine (MSHA I.D. No. 36–08893) located in Schuylkill County, Pennsylvania; B & B Rockridge Slope, Rockridge No. 1 Slope Mine (MSHA I.D. No. 36–07741) located in Schuylkill County, Pennsylvania; Chestnut Coal Company, No. 10 Slope Mine (MSHA I.D. No. 36–07059) located in Northumberland County, Pennsylvania; D & D Coal Company, Primrose Slope Mine (MSHA I.D. No. 36–08341) located in Schuylkill County, Pennsylvania; F.K.Z Coal Company, No. 1 Slope Mine (MSHA I.D. No. 36–08637) located in Northumberland County, Pennsylvania; Joliett Coal Company, #3 Vein Slope Mine (MSHA I.D. No. 36–08702) located in Schuylkill County, Pennsylvania; Little Buck Coal Company, No. 2 Slope Mine (MSHA I.D. No. 36–08299) located in Schuylkill County, Pennsylvania; R & D Coal Company, R & D Coal Co., Inc. Mine (MSHA I.D. No. 36–02053) located in Schuylkill County, Pennsylvania; R S & W Coal Co., Inc., R S & W Drift Mine (MSHA I.D. No. 36–01818) located in Schuylkill County, Pennsylvania; Orchard Coal Company, Orchard Slope Mine (MSHA I.D. No. 36–08346) located in Schuylkill County, Pennsylvania; Snyder Coal Company, N & L Slope Mine (MSHA I.D. No. 36–02203) located in Northumberland County, Pennsylvania; Snyder Coal Company, Rock Slope #1 Mine (MSHA I.D. No. 36–09256) located in Northumberland County, Pennsylvania; Tito Coal Company, Whites Vein Slope Mine (MSHA I.D. No. 36–06815) located in Schuylkill County, Pennsylvania; UAE Coalcorp Association, Harmony Mine (MSHA I.D. No. 36–07838) located in Northumberland County, Pennsylvania; S & M Coal Company, Buck Mountain Slope Mine (MSHA I.D. No. 36–02022) located in Dauphin County, Pennsylvania; R & R Coal Company, R & R Coal Company Mine (MSHA I.D. No. 36–08498) located in Schuylkill County, Pennsylvania; Six M Coal Company, No. 1 Slope Mine (MSHA I.D. No. 36–09138) located in Dauphin County, Pennsylvania; Bear Gap Coal Company, Bear Gap Coal Company #6 Slope Mine (MSHA I.D. No. 36–09296) located in Dauphin County, Pennsylvania. The petitioner requests a modification of the existing standard to permit the reduction of twelve self-contained oxygen breathing apparatus to eight self-contained breathing apparatus, and the reduction of twelve permissible cap lamps and charging rack to eight permissible cap lamps and charging rack. The petitioner states that reduction of two rescue teams with five members and one alternate to two rescue teams of three members with one alternative has been granted to all operating anthracite coal mines. The petitioner asserts that eight self-contained breathing apparatus and eight permissible cap lamps are sufficient to supply the seven members of the rescue team, and that the proposed alternate method of compliance will not alter, change, or reduce the ability, effectiveness, or safety of the underground mine personnel.

2. Bear Gap Coal Company

[Docket No. M–2005–086–C]

Bear Gap Coal Company, Box 64 Kushwa Road, Spring Glen, Pennsylvania 17978 has filed a petition to modify the application of 30 CFR 49.2(b) (Availability of mine rescue teams) to its Bear Gap Coal Company #6 Slope Mine (MSHA I.D. No. 36–09296) located in Dauphin County, Pennsylvania. The petitioner requests a modification of the existing standard to permit the reduction of two mine rescue teams with five members and one alternate each to two mine rescue teams of three members with one alternate for either team. The petitioner asserts that application of the existing standard will result in a diminution of safety to the miners, and that the proposed alternative method would provide at least the same measure of protection as the existing standard.

3. Oxbow Mining, LLC

[Docket No. M–2006–001–C]

Oxbow Mining, LLC, P.O. Box 535, 3737 Highway 133, Somerset, Colorado 81434 has filed a petition to modify the application of 30 CFR 75.1726(a) (Performing work from a raised position; safeguards) to its Elk Creek Mine (MSHA I.D. No. 05–04674) located in Gunnison County, Colorado. The petitioner proposes to modify existing scoops for use as mobile work platforms and implement operational restrictions to safeguard miners working from the raised platform. The petitioner states that this petition will apply only to Wagner ST3.5 Scoops, Serial Nos. SA04C0228, Company ID No. 24–25 and SA 04P0292, Company ID No. 24–26. The petitioner has listed in this petition specific terms and conditions that will be used when the proposed alternative is implemented. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

4. Twentymile Coal Company

[Docket No. M–2006–002–C]

Twentymile Coal Company, 29515 Routt County Road #27, Oak Creek, Colorado 80467 has filed a petition to modify the application of 30 CFR 75.500(d) (Permissible electric equipment) to its Foidel Creek Mine (MSHA I.D. No. 05–03836) located in Routt County, Colorado. The petitioner requests a modification of the existing standard to permit an alternative method of compliance to use battery-powered non-permissible hand-held computers in or inby the last open crosscut, including in the return airways, to allow supervisors and selected miners to collect and record data pertinent to safety observations during work processes. The petitioner states that the recorded data in the hand-held computers will be downloaded at the end of the shift and collated with other data to allow the petitioner to proactively correct unsafe practices and to prevent accidents before they occur. The petitioner has listed in this petition specific terms and conditions that will be used when the proposed alternative method is implemented. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

5. Twentymile Coal Company

[Docket No. M–2006–003–C]

Twentymile Coal Company, 29515 Routt County Road #27, Oak Creek, Colorado 80467 has filed a petition to modify the application of 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility) to its Foidel Creek Mine (MSHA I.D. No. 05–03836) located in Routt County, Colorado. The petitioner requests a modification of the existing standard to permit an alternative method of compliance to use battery-powered non-permissible hand-held

computers in or inby the last open crosscut, including in the return airways, to allow supervisors and selected miners to collect and record data pertinent to safety observations during work processes. The petitioner states that the recorded data in the hand-held computers will be downloaded at the end of the shift and collated with other data to allow the petitioner to proactively correct unsafe practices and to prevent accidents before they occur. The petitioner has listed in this petition specific terms and conditions that will be used when the proposed alternative method is implemented. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

Request for Comments

Persons interested in these petitions are encouraged to submit comments via E-mail: *zzMSHA-Comments@dol.gov*; Fax: (202) 693–9441; or Regular Mail/Hand Delivery/Courier: Mine Safety and Health Administration, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209. All comments must be postmarked or received in that office on or before February 23, 2006. Copies of these petitions are available for inspection at that address.

Dated at Arlington, Virginia this 18th day of January 2006.

Robert F. Stone,

Acting Director, Office of Standards, Regulations, and Variances.

[FR Doc. E6–828 Filed 1–23–06; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Privacy Act of 1974, as Amended; System of Records Notices

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of a proposed new routine use for an existing privacy system of records and the revision of the existing inventory of Privacy Act system managers.

SUMMARY: The National Archives and Records Administration (NARA) is proposing to revise an existing system of records, NARA 1—Researcher Application Files. The system is being revised to add as a routine use the invitation for researchers to participate in voluntary customer satisfaction surveys. NARA is also revising its inventory of system managers, Appendix B, to reflect organizational changes and to update addresses.

DATES: *Effective Date:* The revision to NARA 1, Researcher Application Files, will become effective without further notice on February 23, 2006, unless comments received on or before that date cause a contrary decision. If changes are made based on NARA's review comments received, a new final notice will be published.

ADDRESSES: Send comments to the Privacy Act Officer, Office of General Counsel (NGC), Room 3110, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. They may be faxed to 301–837–0293. You may also comment via the Internet to *comments@NARA.GOV.*

FOR FURTHER INFORMATION CONTACT: Ramona Branch Oliver, Privacy Act Officer, National General Counsel, Room 3110, AII, at telephone number 301–837–2024 or fax number 301–837–0293.

SUPPLEMENTARY INFORMATION: The last notice for this system was published in the **Federal Register** on April 2, 2002.

The notice for this system of records states the name and the location of the record system, the authority for and manner of its operation, the categories of individuals that it covers, the types of records that it contains, the sources of information in the records, and the proposed ''routine uses'' of the system of records. The notice also includes the business address of the NARA official who will inform interested persons of the procedures whereby they may gain access to and correct records pertaining to themselves.

One of the purposes of the Privacy Act, as stated in section 2(b)(4) of the Act, is to provide certain safeguards for an individual against an invasion of personal privacy by requiring Federal agencies to disseminate any record of identifiable personal information in a manner that assures that such action is for a necessary and lawful purpose, that information is current and accurate for its intended use, and that adequate safeguards are provided to prevent misuse of such information. NARA intends to follow these principles in transferring information to another agency or individual as a ''routine use'', including assurance that the information is relevant for the purposes for which it is transferred.

Dated: January 14, 2006.

Allen Weinstein,

Archivist of the United States.

Accordingly, we are publishing the revised system of records notice in its entirety and the revised Appendix B as follows:

NARA 1

SYSTEM NAME:

Researcher Application Files.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Researcher application files are maintained in the following locations in the Washington, DC area and other geographical regions. The addresses for these locations are listed in Appendix B following the NARA Notices:

(1) Customer Services Division;

(2) Presidential libraries and projects; and

(3) Regional records services facilities.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system include persons who apply to use original records for research in NARA facilities in the Washington, DC area, the Presidential libraries, and the regional records services facilities.

CATEGORIES OF RECORDS IN THE SYSTEM:

Researcher application files may include: Researcher applications; related correspondence; and electronic records. These files may contain the following information about an individual: Name, address, telephone number, proposed research topic(s), occupation, name and address of employer/institutional affiliation, educational level and major field, expected result(s) of research, photo, researcher card number, type of records used, and other information furnished by the individual. Electronic systems may also contain additional information related to the application process.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C. 2108, 2111 note, and 2203(f)(1).

PURPOSE(S):

The information in this system is used to register researchers who wish to gain access to original records; to assist NARA in maintaining intellectual control over archival holdings and to refer related information to the Office of Inspector General if original records are determined to be missing or mutilated; to disseminate information related to events and programs of interest to NARA's researchers as appropriate; and measure customer satisfaction with NARA services. Aggregate information from this system may be used for the purposes of review, analysis, planning, and policy formulation related to

customer service staffing and facility needs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

NARA maintains researcher application files on individuals to: Register persons who apply to use original records for research at a NARA facility; record initial research interests of researchers; determine which records researchers may want to use; contact researchers if additional information of research interest is found or if problems with the requested records are discovered; and prepare mailing lists for sending notices of events and programs of interest to researchers, including the fundraising and related activities of NARA-associated foundations, and invitations to participate in voluntary customer satisfaction surveys, unless individuals elect that their application information not be used for this purpose. The electronic databases serve as finding aids to the applications. Information in the system is also used by NARA staff to compile statistical and other aggregate reports regarding researcher use of records.

The routine use statements A, C, E, F, and G, described in Appendix A following the NARA Notice, also apply to this system of records.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

In addition to the routine use statements referenced above, the researcher application files are handled consistent with disclosure provisions in 5 U.S.C. 552a(b)(1) through (b)(12).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and electronic records.

RETRIEVABILITY:

Information in the records may be retrieved by the name of the individual or by researcher card number.

SAFEGUARDS:

During normal hours of operation, paper records are maintained in areas accessible only to authorized personnel of NARA. Electronic records are accessible via passwords from terminals located in attended offices. After hours, buildings have security guards and/or doors are secured and all entrances are monitored by electronic surveillance equipment.

RETENTION AND DISPOSAL:

Researcher application files are temporary records and are destroyed in accordance with the disposition instructions in the NARA records schedule contained in FILES 203, the NARA Files Maintenance and Records Disposition Manual. Individuals may request a copy of the disposition instructions from the NARA Privacy Act Officer.

SYSTEM MANAGER(S) AND ADDRESS:

For researchers who apply to use records and Nixon presidential materials in the Washington, DC area, the system manager for researcher application files is: Assistant Archivist for Records Services—Washington, DC (NW). For researchers who apply to use accessioned records, presidential records, and donated historical materials in the Presidential libraries and the regional records services facilities, the system managers of researcher application files are the directors of the individual libraries and regional records services facilities. The addresses for these locations are listed in Appendix B following the NARA Notices.

NOTIFICATION PROCEDURE:

Individuals interested in inquiring about their records should notify the NARA Privacy Act Officer, whose address is listed in Appendix B after the NARA Notices.

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to their records should submit their request in writing to the NARA Privacy Act Officer at the address given in Appendix B.

CONTESTING RECORD PROCEDURES:

NARA rules for contesting the contents and appealing initial determinations are found in 36 CFR part 1202.

RECORD SOURCE CATEGORIES:

Information in researcher application files is obtained from researchers and from NARA employees who maintain the files.

EXEMPTIONS CLAIMED FOR THE SYSTEM: NONE

Appendix A—Routine Uses

The following routine use statements will apply to National Archives and Records Administration notices where indicated:

A. Routine Use—Law Enforcement

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records, may be referred, as a routine use, to the appropriate agency, whether Federal, State, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

B. Routine Use—Disclosure When Requesting Information

A record from this system of records may be disclosed as a routine use to a Federal, State, or local agency maintaining civil, criminal or other relevant enforcement information or other pertinent information, such as current licenses, if necessary, to obtain information relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

C. Routine Use—Disclosure of Requested Information

A record from this system of records may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, conducting a security or suitability investigation, classifying a job, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

D. Routine Use—Grievance, Complaint, Appeal

A record from this system of records may be disclosed to an authorized appeal or grievance examiner, formal complaints examiner, equal employment opportunity investigator, arbitrator, or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee. A record from this system of records may be disclosed to the United States Office of Personnel Management, the Merit Systems Protection Board, Federal Labor Relations Authority, or the Equal Employment Opportunity Commission when requested in the performance of their authorized duties. To the extent that official personnel records in the custody of NARA are covered within the system of records published by the Office of Personnel Management as Governmentwide records, those records will be considered as a part of that Governmentwide system. Other records covered by notices published by NARA and considered to be separate systems of records may be transferred to the Office of Personnel Management in accordance with official personnel programs and activities as a routine use.

E. Routine Use—Congressional Inquiries

A record from this system of records may be disclosed as a routine use to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the request of the individual about whom the record is maintained.

F. Routine Use—NARA Agents

A record from this system of records may be disclosed as a routine use to an expert, consultant, agent, or a contractor of NARA to the extent necessary for them to assist NARA in the performance of its duties. Agents include, but are not limited to, GSA or other entities supporting NARA's payroll, finance, and personnel responsibilities.

G. Routine Use—Department of Justice/ Courts

A record from this system of records may be disclosed to the Department of Justice or in a proceeding before a court or adjudicative body before which NARA is authorized to appear, when: (a) NARA, or any component thereof; or, (b) any employee of NARA in his or her official capacity; or, (c) any employee of NARA in his or her individual capacity where the Department of Justice or NARA has agreed to represent the employee; or (d) the United States, where NARA determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or by NARA before a court or adjudicative body is deemed by NARA to be relevant and necessary to the litigation, provided, however, that in each case, NARA determines that disclosure of the records is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

Appendix B

To inquire about your records or to gain access to your records, you should submit your request in writing to: NARA Privacy Act Officer, Office of General Counsel (NGC), National Archives at College Park, 8601 Adelphi Road, Room 3110, College Park, MD 20740–6001.

If the system manager is the Assistant Archivist for Record Services—Washington, DC (NW), the records are located at the following address: Office of Record Services—Washington, DC (NW), National Archives at College Park, 8601 Adelphi Road, Room 3400, College Park, MD 20740–6001.

If the system manager is the director of a Presidential Library, the records are located at the appropriate Presidential Library, Staff or Project:

George Bush Library, 1000 George Bush Drive West, College Station, TX 77845.

Jimmy Carter Library, 441 Freedom Parkway, Atlanta, GA 30307–1498.

William J. Clinton Presidential Library, 1200 President Clinton Avenue, Little Rock, AR 72201.

Dwight D. Eisenhower Library, 200 SE 4th Street, Abilene, KS 67410–2900.

Gerald R. Ford Library, 1000 Beal Avenue, Ann Arbor, MI 48109–2114.

Herbert Hoover Library, 210 Parkside Drive, P.O. Box 488, West Branch, IA 52358–0488.

Lyndon B. Johnson Library, 2313 Red River Street, Austin, TX 78705–5702.

John F. Kennedy Library, Columbia Point, Boston, MA 02125–3398.

Nixon Presidential Materials Staff, National Archives at College Park, 8601 Adelphi Road, Room 1320, College Park, MD 20740–6001.

Ronald Reagan Library, 40 Presidential Drive, Simi Valley, CA 93065–0600.

Franklin D. Roosevelt Library, 4079 Albany Post Road, Hyde Park, NY 12538–1999.

Harry S. Truman Library, 500 West US Highway 24, Independence, MO 64050–1798.

Office of Presidential Libraries, National Archives at College Park, 8601 Adelphi Road, Room 2200, College Park, MD 20740–6001.

If the system manager is the director of a Federal Records Center or Regional Archives facility, the records are located at the appropriate Federal Records Center or Regional Archives Facility:

NARA's Pacific Alaska Region (Anchorage), 654 West Third Avenue, Anchorage, Alaska 99501–2145.

NARA's Southeast Region (Atlanta), 5780 Jonesboro Road, Morrow, Georgia 30260.

NARA's Northeast Region (Boston), Frederick C. Murphy Federal Center, 380 Trapelo Road, Waltham, Massachusetts 02452–6399.

NARA's Great Lakes Region (Chicago), 7358 South Pulaski Road, Chicago, Illinois 60629–5898.

NARA's Great Lakes Region (Dayton), 3150 Springboro Road, Dayton, Ohio 45439–1883.

NARA's Rocky Mountain Region (Denver), Bldg. 48, Denver Federal Center, West 6th Avenue and Kipling Street, Denver, Colorado 80225–0307.

NARA's Southwest Region (Fort Worth), 501 West Felix Street, Building 1, Fort Worth, Texas 76115–3405.

NARA's Central Plains Region (Kansas City), 2312 East Bannister Road, Kansas City, Missouri 64131–3.

NARA's Pacific Region (Laguna Niguel, CA), 24000 Avila Road, 1st Floor, East Entrance, Laguna Niguel, California 92677–3497.

NARA's Central Plains Region (Lee's Summit, MO), 200 Space Center Drive, Lee's Summit, Missouri 64064–1182.

NARA's Northeast Region (New York City), 201 Varick Street, New York, New York 10014–4811.

NARA's Mid Atlantic Region (Center City Philadelphia), 900 Market Street, Philadelphia, Pennsylvania 19107–4292.

NARA's Mid Atlantic Region (Northeast Philadelphia), 14700 Townsend Road, Philadelphia, Pennsylvania 19154–1096.

NARA's Mid Atlantic Region (Center City Philadelphia), 900 Market Street, Philadelphia, Pennsylvania 19107–4292.

NARA's Northeast Region (Pittsfield, MA), 10 Conte Drive, Pittsfield, Massachusetts 01201–8230.

NARA's Pacific Region (San Francisco), 1000 Commodore Drive, San Bruno, California 94066–2350.

NARA's Pacific Alaska Region (Seattle), 6125 Sand Point Way NE., Seattle, Washington 98115–7999.

National Personnel Records Center, Civilian Personnel Records, 111 Winnebago Street, St. Louis, Missouri 63118–4126.

National Personnel Records Center, Military Personnel Records, 9700 Page Avenue, St. Louis, MO 63132–5100.

Washington National Records Center (WNRC), 4205 Suitland Road, Suitland, MD 20746–8001.

If the system manager is the Director of the National Historical Publications and Records Commission (NHPRC), the records are located at the following address:

National Historical Publications and Records Commission (NHPRC), National Archives and Records Administration, 700 Pennsylvania Avenue, NW., Room 111, Washington, DC 20408–0001.

If the system manager is the Director of the Policy and Planning Staff, the records are located at the following address: Policy and Planning Staff (NPOL), National Archives and Records Administration, 8601 Adelphi Road, Room 4100, College Park, MD 20740–6001.

If the system manager is the Director of the Congressional Affairs and Communications Staff, the records are located at the following address: Congressional Affairs and Communications Staff (NCON), National Archives and Records Administration, 700 Pennsylvania Avenue, NW., Room 102, Washington, DC 20408–0001.

If the system manager is the Assistant Archivist for Information Services, the records are located at the following address: Office of Information Services (NH), National Archives and Records Administration, 8601 Adelphi Road, Room 4400, College Park, MD 20740.

If the system manager is the Assistant Archivist for Administration, the records are located at the following address: Office of Administration (NA), National Archives and Records Administration, 8601 Adelphi Road, Room 4200, College Park, MD 20740.

If the system manager is the Director of the Federal Register, the records are located at the following address: Office of the Federal Register (NF), National Archives and Records Administration, 700 Pennsylvania Avenue, NW, Washington, DC 20408–0001.

If the system manager is the Inspector General, the records are located at the following address: Office of the Inspector General (OIG), National Archives and Records Administration, 8601 Adelphi Road, Room 1300, College Park, MD 20740.

If the system manager is the General Counsel, the records are located at the following address: Office of the General Counsel (NGC), National Archives and Records Administration, 8601 Adelphi Road, Room 3110, College Park, MD 20740.

[FR Doc. E6–798 Filed 1–23–06; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATE: Weeks of January 23, 30, February 6, 13, 20, 27, 2006.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

MATTERS TO BE CONSIDERED:

Week of January 23, 2006

There are no meetings scheduled for the Week of January 23, 2006.

Week of January 30, 2006—Tentative

Tuesday, January 31, 2006

9:25 a.m.—Affirmation Session (Public Meeting).

a. FIRSTENERGY Nuclear Operating Co. (Beaver Valley Power Station, Unit Nos. 1&2; Davis Besse Power Station, Unit 1; Perry Nuclear Power Plant, Unit No. 1), Docket Nos. 50–334–LT, 50–346–LT, 50–412–LT, & 50–440–LT.

b. Private Fuel Storage (Independent Spent Fuel Storage Installation) Docket No. 72–22–ISFSI (Tentative).

c. Motion to Reopen the Millstone License Renewal Proceedings Filed by Connecticut Coalition Against Millstone (Tentative).

9:30 a.m.—Briefing on Strategic Workforce Planning and Human Capital Initiatives (Public Meeting). (Contact: Kristen Davis, 301–415–7108.)

This meeting will be Webcast live at the Web address—*http://www.nrc.gov*.

Wednesday, February 1, 2006

9:30 a.m.—Discussion of Security Issues (Closed—Ex. 1 & 3).

Week of February 6, 2006—Tentative

Monday, February 6, 2006

9:30 a.m.—Briefing on Materials Degradation Issues and Fuel Reliability (Public Meeting). (Contact: Jennifer Uhle, 301–415–6200.)

This meeting will be Webcast live at the Web address—*http://www.nrc.gov*.

2 p.m.—Discussion of Security Issues (Closed—Ex. 1 & 3).

Wednesday, February 8, 2006

9:30 a.m.—Briefing on Office of Nuclear Materials Safety and Safeguards (NMSS). Programs, Performance, and Plans—Materials Safety (Public Meeting). (Contact: Teresa Mixon, 301–415–7474; Derek Widmayer, 301–415–6677.)

This meeting will be Webcast live at the Web address—*http://www.nrc.gov*.

1:30 p.m.—Briefing on Office of Research (RES) Programs, Performance and Plans (Public Meeting). (Contact: Gene Carpenter, 301–415–7333.)

This meeting will be Webcast live at the Web address—*http://www.nrc.gov*.

Week of February 13, 2006—Tentative

Tuesday, February 14, 2006

2 p.m.—Briefing on Office of Nuclear Materials Safety and Safeguards (NMSS). Programs, Performance, and Plans—Waste Safety (Public Meeting). (Contact: Teresa Mixon, 301–415–7474; Derek Widmayer, 301–415–6677.)

This meeting will be Webcast live at the Web address—*http://www.nrc.gov*.

Wednesday, February 15, 2006

9:30 a.m.—Briefing on Office of Chief Financial Officer (CFO) Programs, Performance, and Plans (Public Meeting). (Contact: Edward New, 301–415–5646.)

This meeting will be Webcast live at the Web address—*http://www.nrc.gov*.

Week of February 20, 2006—Tentative

There are no meetings scheduled for the Week of February 20, 2006.

Week of February 27, 2006—Tentative

There are no meetings scheduled for the Week of February 27, 2006.

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Michelle Schroll, (301) 415–1662.

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/what-we-do/policy-making/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify the NRC's Disability Program Coordinator, August Spector, at 301–415–7080, TDD: 301–415–2100, or by e-mail at *aks@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov.*

Dated: January 19, 2006.

R. Michelle Schroll,

Office of the Secretary.

[FR Doc. 06–698 Filed 1–20–06; 11:05 am]

BILLING CODE 7590–01–M

POSTAL RATE COMMISSION

[Docket No. MC2006–2; Order No. 1452]

Repositionable Notes Minor Classification Changes

AGENCY: Postal Rate Commission.

ACTION: Notice and order.

SUMMARY: This document establishes a formal docket to consider extending the one-year Repositionable Notes market test beyond its scheduled expiration in early April 2006. The Service seeks the extension because it had planned to file a new request involving a modified Repositionable Notes service prior to the expiration of the current test, but would like to complete a review of a recently-filed academic research paper before doing so. Extending the current test would allow this review to take place and for the anticipated new request to be adjusted, if warranted, without the disruption associated with expiration of the current test.

DATES: See **SUPPLEMENTARY INFORMATION** for dates.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.*

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, general counsel, at 202–789–6818.

SUPPLEMENTARY INFORMATION:

Regulatory History

Docket No. MC2004–5, 68 FR 45353 (July 29, 2004).

I. Background

Notice is hereby given that on January 12, 2006, the Postal Service filed a request with the Postal Rate Commission pursuant to section 3623 of the Postal Reorganization Act, 39 U.S.C. 101 *et seq.*, for a recommended decision on its request for an extension of the current provisional Repositionable Notes (RPN) service.[1] The Postal Service denominates this request a minor classification change and seeks to have it considered under the Commission's

[1] Request of the United States Postal Service for a Recommended Decision on Change of Expiration Date for Provisional Repositionable Notes Classifications and Rates, filed January 12, 2006.

rules for expedited minor classification cases (39 CFR 3001.69).

The Postal Service's extension request indicates that it had been finalizing a request for further testing of a modified RPN service that would address the suggestions made by the Commission in its Opinion in Docket No. MC2004–5. The request observes that on January 6, 2006, the Postal Service received a copy of the Commission-sponsored white paper addressing various issues raised by the RPN service from an academic perspective. The request states that the Postal Service decided to delay finalizing its request for a modified RPN service in order to incorporate consideration of the white paper. The Postal Service explains its decision to incorporate consideration of the white paper in its request makes it impossible to process a request for testing of a modified RPN service prior to the scheduled expiration of the provisional RPN service on April 3, 2006. The Postal Service asks the Commission to approve an extension of that service in order to avoid disruption to customers that would be caused by termination of the provisional RPN service on April 3, 2006, pending consideration of the next phase of the service.

The Postal Services proposes that the status quo continue until a replacement provisional or permanent service is implemented, or, if no such service is implemented, three months after the Commission takes action on a Postal Service request to implement such a service. If the Postal Service does not file such a request, the proposal is that the provisional service expire on April 3, 2007. See page 2 and Attachment A of the Request. The request includes attachments and is supported by the testimony of witness Kirk Kaneer. It also includes a conditional motion for waiver of rule 64 of our rules of practice, if material incorporated from Docket No. R2005–1 is not considered adequate to satisfy that rule. The request is on file in the Commission's docket room for inspection during regular business hours and is available on the Commission's Web site at *http://www.prc.gov.*

II. Settlement

Proposed settlement procedures. The Postal Service requests that the Commission establish settlement procedures in this proceeding. It argues that settlement of issues surrounding its request is appropriate, since the purpose of the extension of the status quo is to allow a modified RPN service to reflect the white paper and the public dialogue that the white paper is intended to foster to be considered in designing the modified service.

The Commission will appoint Postal Service counsel to serve as settlement coordinator in this proceeding. In this capacity, counsel for the Postal Service shall report on the status of settlement discussions at the prehearing conference. The Commission will make its hearing room available for settlement conferences at such times deemed necessary by the settlement coordinator. If someone intervenes after a settlement conference is held, the settlement coordinator could brief such person on the substance of the conference.

III. Expedition

Further procedures. Rule 69b affords all interested parties 26 days after filing of the Postal Service's request (February 7, 2006) to intervene and respond to the Postal Service's proposal to have this request considered under the expedited procedures of rule 69. On February 8, 2006, the Commission will determine if expedited rule 69 procedures are appropriate. If the Commission determines that they are, intervenors will have until February 23, 2006, to state with specificity those issues of material fact, if any, that they contend require a hearing, the period that rule 69b(h) allows. They may make their statement in writing, or orally at the prehearing conference, provisionally scheduled for February 23. If the Commission determines that hearings are warranted, they will commence on March 1, 2006, the period that rule 69b(i) allows. If no hearing is necessary, a recommended decision will be issued promptly.

IV. Public Participation

Public participation. In conformance with section 3624(a) of title 39, the Commission designates Shelley S. Dreifuss, director of the Commission's Office of the Consumer Advocate (OCA), to represent the interests of the general public in this proceeding. Pursuant to this designation, Ms. Dreifuss will direct the activities of Commission personnel assigned to assist her and, upon request, will supply their names for the record. Neither Ms. Dreifuss nor any of the assigned personnel will participate in or provide advice on any Commission decision in this proceeding.

V. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. MC2006–2 to consider the Postal Service Request referred to in the body of this order.
2. The Commission will act en banc in this proceeding.
3. Notices of intervention shall be filed no later than February 7, 2006.
4. Shelley S. Dreifuss, director of the Commission's Office of the Consumer Advocate, is designated to represent the interests of the general public.
5. Answers to the Postal Service's Conditional Motion for Waiver of the portions of rule 64 are due on February 7, 2006.
6. Postal Service counsel is appointed to serve as settlement coordinator in this proceeding. The Commission will make its hearing room available for settlement conferences at such times deemed necessary by the settlement coordinator.
7. A prehearing conference is provisionally scheduled for February 23, 2006, at 11 a.m. in the Commission's hearing room.
8. Participants who wish to request a hearing on the Postal Service's request in this docket to extend its market test shall submit such a request, together with statements in conformance with 39 CFR 3001.69b(h) on or before February 23, 2006.
9. The Secretary shall cause this notice and order to be published in the **Federal Register**.

By the Commission.

Steven W. Williams,

Secretary.

[FR Doc. 06–609 Filed 1–23–06; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 15c2–1; SEC File No. 270–418; OMB Control No. 3235–0485.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*,) the Securities and Exchange Commission (''Commission'') is publishing the following summaries of collections for public comment.

Rule 15c2–1 prohibits the commingling under the same lien of securities of margin customers (a) with other customers without their written consent and (b) with the broker or dealer. The rule also prohibits the rehypothecation of customers' margin securities for a sum in excess of the customer's aggregate indebtedness. *See* Securities Exchange Act Release No.

2690 (November 15, 1940); Securities Exchange Act Release No. 9428 (December 29, 1971). Pursuant to Rule 15c2–1, respondents must collect information necessary to prevent the rehypothecation of customer securities in contravention of the rule, issue and retain copies of notices of hypothecation of customer securities in accordance with the rule, and collect written consents from customers in accordance with the rule. The information is necessary to ensure compliance with the rule, and to advise customers of the rule's protections.

There are approximately 145 respondents (*i.e.,* broker-dealers that carry or clear customer accounts that also have bank loans) that require an aggregate total of 3263 hours to comply with the rule. Each of these approximately 145 registered broker-dealers makes an estimated 45 annual responses. Each response takes approximately 0.5 hours to complete. Thus, the total compliance burden per year is 3263 burden hours.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Direct your written comments to R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 100 F Street, NW., Washington, DC 20549.

Dated: January 17, 2006.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 06–622 Filed 1–23–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53131; File No. S7–24–89]

Joint Industry Plan; Notice of Filing and Immediate Effectiveness of Amendment Nos. 15 and 16 to the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privileges Basis, Submitted by the Pacific Exchange, Inc., the National Association of Securities Dealers, Inc., the American Stock Exchange LLC, the Boston Stock Exchange, Inc., the Chicago Stock Exchange, Inc., the National Stock Exchange, Inc., and the Philadelphia Stock Exchange, Inc.

January 17, 2006.

I. Introduction and Description

Pursuant to Rule 608 of the Securities Exchange Act of 1934 (the ''Act'') [1] notice is hereby given that on December 15, 2005, the operating committee (''Operating Committee'' or ''Committee'') [2] of the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation, and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privilege Basis (''Nasdaq/UTP Plan'' or ''Plan'') filed with the Securities and Exchange Commission (''Commission'') amendments to the Plan. These amendments are incorporated in Amendment 15 to the Plan and reflect elimination of the New York Stock Exchange as a Plan Participant, removal of an outdated section of the Plan regarding Eligible Securities, and modification of Exhibit 1 to the Plan to reflect quarterly year-to-date payments and adjustments of distributable net operating income. Amendment 15 was unanimously approved by the Committee on September 22, 2005.[3] In addition, pursuant to Rule 608 of the Act, notice is hereby given that on December 23, 2005, the Committee filed with the Commission another amendment to the Plan, Amendment 16. Amendment 16 to the Plan reflects the addition of the International Securities Exchange as a Plan Participant. Amendment 16 was unanimously approved by the Committee on November 17, 2005.[4] The Commission is publishing this notice of filing and immediate effectiveness to solicit comments from interested persons on Amendment Nos. 15 and 16.

II. Background

The Plan governs the collection, consolidation, and dissemination of quotation and transaction information for the Nasdaq Stock Market, Inc. (''Nasdaq'') National Market (''NNM'') and Nasdaq SmallCap securities listed on Nasdaq or traded on an exchange pursuant to unlisted trading privileges (''UTP'').[5] The Plan provides for the collection from Plan Participants and the consolidation and dissemination to vendors, subscribers, and others of quotation and transaction information in Eligible Securities.[6]

The Commission originally approved the Plan on a pilot basis on June 26, 1990.[7] The parties did not begin trading until July 12, 1993; accordingly, the pilot period commenced on July 12, 1993. The Plan was most recently extended on December 14, 2005.[8]

[1] 17 CFR 242.608.

[2] The Plan Participants (collectively, ''Participants'') are: The American Stock Exchange, LLC (''AMEX''), the Boston Stock Exchange, Inc. (''BSE''), the Chicago Board Options Exchange, Inc. (''CBOE''), the Chicago Stock Exchange, Inc. (''CHX''), the National Stock Exchange, Inc. (''NSX''), the National Association of Securities Dealers, Inc. (''NASD''), the Pacific Exchange (''PCX''), and the Philadelphia Stock Exchange, Inc. (''PHLX'').

[3] *See* letter from Bridget M. Farrell, Chairman, OTC/UTP Operating Committee, to Jonathan G. Katz, Secretary, Commission, dated December 14, 2005.

[4] *See* letter from Bridget M. Farrell, Chairman, OTC/UTP Operating Committee, to Jonathan G. Katz, Secretary, Commission, dated December 20, 2005.

[5] Section 12 of the Act generally requires an exchange to trade only those securities that the exchange lists, except that section 12(f) of the Act permits UTP under certain circumstances. For example, section 12(f) of the Act, among other things, permits exchanges to trade certain securities that are traded over-the-counter (''OTC/UTP''), but only pursuant to a Commission order or rule. For a more complete discussion of the section 12(f) requirement, *see* Securities Exchange Act Release No. 36481 (November 13, 1995), 60 FR 58119 (November 24, 1995).

[6] The Plan defines ''Eligible Securities'' as any Nasdaq National Market or Nasdaq SmallCap security, as defined in NASD Rule 4200, (i) as to which unlisted trading privileges have been granted to a national securities exchange pursuant to section 12(f) of the Act or which become eligible for such trading pursuant to order of the Commission, or (ii) which is also listed on a national securities exchange.

[7] *See* Securities Exchange Act Release No. 28146, 55 FR 27917 (July 6, 1990).

[8] *See* Securities Exchange Act Release No. 52886, 70 FR 74059 (December 14, 2005).

III. Description and Purpose of the Amendments [9]

A. Amendment No. 15

The following is a summary of the changes to the Plan prepared by the Participants:

(i) Section I.A. of the Plan provides for the list of Plan Participants. Amendment 15 eliminates the New York Stock Exchange (''NYSE'') as a Plan Participant.

(ii) Section VI.C.2 of the Plan provides for a phase-in of Eligible Securities and certain Auto-Quoting restrictions that are no longer relevant. Accordingly, Amendment 15 proposes to delete this section of the Plan.

(iii) Section VI.C.3 and Section VI.C.4 shall be renumbered due to the elimination of section VI.C.2.

(iv) Section VIII.C sets forth the symbols for market identification for quotation information and transaction reports. Amendment 15 eliminates ''N'' as a symbol, since NYSE is being eliminated as a plan participant.

(v) Amendment 15 also modifies Exhibit 1 to the Plan to reflect that Participants will be provided with written estimates of estimated quarterly net distributable operating income within 45 calendar days of the end of the quarter and estimated quarterly payments shall be made on the basis of such estimates.

(vi) Further, Exhibit 1 has been modified to reflect that each quarterly payment shall be reconciled against a Participant's cumulative year-to-date payment received to date and adjusted accordingly. Lastly, Amendment 15 clarifies language regarding interest payments and audit adjustment procedures.

B. Amendment No. 16

Section I.A. of the Plan provides for the list of Plan Participants. Amendment 16 adds the International Securities Exchange (''ISE'') as a Plan Participant. ISE will commence quoting and trading in Nasdaq-listed securities upon completing the necessary development and implementation work required to become a new Participant in Nasdaq-listed securities. ISE has paid the Plan entrance fee pursuant to section XIII.A.

IV. Date of Effectiveness of the Amendment

The changes set forth in Amendment Nos. 15 and 16 are concerned solely with the administration of the plan or involve solely technical or ministerial matters, and thus are being put into effect upon filing with the Commission pursuant to Rules 608(b)(3)(ii) and 608(b)(3)(iii).[10] At any time within 60 days of the filing of any such amendment, the Commission may summarily abrogate the amendment and require that such amendment be refiled in accordance with paragraph (a)(1) of Rule 608 under the Act [11] and reviewed in accordance with paragraph (b)(2) of Rule 608 under the Act,[12] if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect mechanisms of, a national market system or otherwise in furtherance of the purposes of the Act.[13]

V. Solicitation of Comments

The Commission seeks general comments on Amendment Nos. 15 and 16. Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number S7–24–89 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number S7–24–89. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the Office of the Secretary of the Committee, currently located at the Pacific Exchange, Inc. and Archipelago Exchange L.L.C., 100 South Wacker Drive, Suite 2000, Chicago, IL 60606. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number S7–24–89 and should be submitted on or before February 14, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Jill M. Peterson,

Assistant Secretary.

Exhibit A

Amendment Nos. 15 and 16; Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privilege Basis.

The undersigned registered national securities association and national securities exchanges (collectively referred to as the ''Participants''), have jointly developed and hereby enter into this Nasdaq Unlisted Trading Privileges Plan (''Nasdaq UTP Plan'' or ''Plan'').

I. Participants

The Participants include the following:

A. Participants

1. American Stock Exchange LLC, 86 Trinity Place, New York, New York 10006.
2. Boston Stock Exchange, 100 Franklin Street, Boston, Massachusetts 02110.
3. Chicago Stock Exchange, 440 South LaSalle Street, Chicago, Illinois 60605.
4. Chicago Board Options Exchange, Inc., 400 South LaSalle Street, 26th Floor, Chicago, Illinois 60605.
5. International Securities Exchange, Inc., 60 Broad Street, New York, New York 60605.
6. National Association of Securities, Dealers, Inc., 1735 K Street, NW., Washington, DC 20006.

[9] The complete text of the Plan, as amended by Amendments No. 15 and 16, is attached as Exhibit A.

[10] 17 CFR 242.608(b)(3)(ii) and (b)(3)(iii).

[11] 17 CFR 242.608(a)(1).

[12] 17 CFR 242.608(b)(2).

[13] 17 CFR 242.608(b)(3)(iii).

[14] 17 CFR 200.30–3(a)(27).

7. National Stock Exchange, 440 South LaSalle Street, 26th Floor, Chicago, Illinois 60605.

8. Pacific Exchange, Inc., 115 Sansome Street, San Francisco, CA 94104.

9. Philadelphia Stock Exchange, 1900 Market Street, Philadelphia, Pennsylvania 19103.

B. Additional Participants

Any other national securities association or national securities exchange, in whose market Eligible Securities become traded, may become a Participant, provided that said organization executes a copy of this Plan and pays its share of development costs as specified in section XIII.

II. Purpose of Plan

The purpose of this Plan is to provide for the collection, consolidation and dissemination of Quotation Information and Transaction Reports in Eligible Securities from the Participants in a manner consistent with the Exchange Act.

It is expressly understood that each Participant shall be responsible for the collection of Quotation Information and Transaction Reports within its market and that nothing in this Plan shall be deemed to govern or apply to the manner in which each Participant does so.

III. Definitions

A. ''Current'' means, with respect to Transaction Reports or Quotation Information, such Transaction Reports or Quotation Information during the fifteen (15) minute period immediately following the initial transmission thereof by the Processor.

B. ''Eligible Security'' means any Nasdaq National Market or Nasdaq SmallCap security, as defined in NASD Rule 4200: (i) As to which unlisted trading privileges have been granted to a national securities exchange pursuant to Section 12(f) of the Exchange Act or which become eligible for such trading pursuant to order of the Securities and Exchange Commission; or (ii) which also is listed on a national securities exchange.

C. ''Commission'' and ''SEC'' shall mean the U.S. Securities and Exchange Commission.

D. ''Exchange Act'' means the Securities Exchange Act of 1934.

E. ''Market'' shall mean (i) when used with respect to Quotation Information, the NASD in the case of a Nasdaq market maker or a Nasdaq-registered electronic communications network/alternative trading system (hereafter collectively referred to as ''Nasdaq market participants'') acting in such capacity, or the Participant on whose floor or through whose facilities the quotation was disseminated; and (ii) when used with respect to Transaction Reports, the Participant through whose facilities the transaction took place or was reported, or the Participant to whose facilities the order was sent for execution.

F. ''NASD'' means the National Association of Securities Dealers Inc.

G. ''NASD Participant'' means an NASD member that is registered as a market maker or an electronic communications network or otherwise utilizes the facilities of the NASD pursuant to applicable NASD rules.

H. ''NASD Transaction Reporting System'' means the System provided for in the NASD's Transaction Reporting Plan filed with and approved by the Commission pursuant to SEC Rule11Aa3–1, governing the reporting of transactions in Nasdaq securities.

I. ''UTP Quote Data Feed'' means the service that provides Subscribers with the National Best Bid and Offer quotations, size and market center identifier, as well as the Best Bid and Offer quotations, size and market center identifier from each individual Participant in Eligible Securities.

J. ''Nasdaq Level 2 Service'' means the Nasdaq service that provides Subscribers with query capability with respect to quotations and sizes in securities included in the Nasdaq System, best bid and asked quotations, and Transaction Reports.

K. ''Nasdaq Level 3 Service'' means the Nasdaq service that provides Nasdaq market participants with input and query capability with respect to quotations and sizes in securities included in the Nasdaq System, best bid and asked quotations, and Transaction Reports.

L. ''Nasdaq System'' means the automated quotation system operated by Nasdaq.

M. ''UTP Trade Data Feed'' means the service that provides Vendors and Subscribers with Transaction Reports.

N. ''Nasdaq Security'' or ''Nasdaq-listed Security'' means any security listed on the Nasdaq National Market or Nasdaq SmallCap Market.

O. ''News Service'' means a person that receives Transaction Reports or Quotation Information provided by the Systems or provided by a Vendor, on a Current basis, in connection with such person's business of furnishing such information to newspapers, radio and television stations and other news media, for publication at least fifteen (15) minutes following the time when the information first has been published by the Processor.

P. ''OTC Montage Data Feed '' means the data stream of information that provides Vendors and Subscribers with quotations and sizes from all Participants and Nasdaq market participants.

Q. ''Participant'' means a registered national securities exchange or national securities association that is a signatory to this Plan.

R. ''Plan'' means this Nasdaq UTP Plan, as from time to time amended according to its provisions, governing the collection, consolidation and dissemination of Quotation Information and Transaction Reports in Eligible Securities.

S. ''Processor'' means the entity selected by the Participants to perform the processing functions set forth in the Plan.

T. ''Quotation Information'' means all bids, offers, displayed quotation sizes, the market center identifiers and, in the case of NASD and Nasdaq, the NASD and Nasdaq market participant that entered the quotation, withdrawals and other information pertaining to quotations in Eligible Securities required to be collected and made available to the Processor pursuant to this Plan.

U. ''Regulatory Halt'' means a trade suspension or halt called for the purpose of dissemination of material news, as described at Section X hereof or that is called for where there are regulatory problems relating to an Eligible Security that should be clarified before trading therein is permitted to continue, including a trading halt for extraordinary market activity due to system misuse or malfunction under Section X.E.1. of the Plan (''Extraordinary Market Regulatory Halt'').

V. ''Subscriber'' means a person that receives Current Quotation Information or Transaction Reports provided by the Processor or provided by a Vendor, for its own use or for distribution on a non-Current basis, other than in connection with its activities as a Vendor.

W. ''Transaction Reports'' means reports required to be collected and made available pursuant to this Plan containing the stock symbol, price, and size of the transaction executed, the Market in which the transaction was executed, and related information, including a buy/sell/cross indicator and trade modifiers, reflecting completed transactions in Eligible Securities.

X. ''Upon Effectiveness of the Plan'' means July 12, 1993, the date on which the Participants commenced publication of Quotation Information and

Transaction Reports on Eligible Securities as contemplated by this Plan.

Y. ''Vendor'' means a person that receives Current Quotation Information or Transaction Reports provided by the Processor or provided by a Vendor, in connection with such person's business of distributing, publishing, or otherwise furnishing such information on a Current basis to Subscribers, News Services or other Vendors.

Z. ''NQDS'' means the data stream of information that provides Vendors and Subscribers with the best quotations and sizes from each Nasdaq Participant.

AA. ''Nasdaq Participant'' means an entity that is registered as a market maker or an electronic communications network in Nasdaq or otherwise utilizes the facilities of The Nasdaq Stock Market pursuant to applicable NASD rules but does not include an NASD Participant as defined in Section III.G. of this Plan.

IV. Administration of Plan

A. Operating Committee: Composition

The Plan shall be administered by the Participants through an operating committee (''Operating Committee''), which shall be composed of one representative designated by each Participant. Each Participant may designate an alternate representative or representatives who shall be authorized to act on behalf of the Participant in the absence of the designated representative. Within the areas of its responsibilities and authority, decisions made or actions taken by the Operating Committee, directly or by duly delegated individuals, committees as may be established from time to time, or others, shall be binding upon each Participant, without prejudice to the rights of any Participant to seek redress from the SEC pursuant to Rule 11Aa3–2 under the Exchange Act or in any other appropriate forum.

An Electronic Communications Network, Alternative Trading System, Broker-Dealer or other securities organization (''Organization'') which is not a Participant, but has an actively pending Form 1 Application on file with the Commission to become a national securities exchange, will be permitted to appoint one representative and one alternate representative to attend regularly scheduled Operating Committee meetings in the capacity of an observer/advisor. If the Organization's Form 1 petition is withdrawn, returned, or is otherwise not actively pending with the Commission for any reason, then the Organization will no longer be eligible to be represented in the Operating Committee meetings. The Operating Committee shall have the discretion, in limited instances, to deviate from this policy if, as indicated by majority vote, the Operating Committee agrees that circumstances so warrant.

Nothing in this section or elsewhere within the Plan shall authorize any person or organization other than Participants and their representatives to participate on the Operating Committee in any manner other than as an advisor or observer, or in any Executive Session of the Operating Committee.

B. Operating Committee: Authority

The Operating Committee shall be responsible for:

1. Overseeing the consolidation of Quotation Information and Transaction Reports in Eligible Securities from the Participants for dissemination to Vendors, Subscribers, News Services and others in accordance with the provisions of the Plan;

2. Periodically evaluating the Processor;

3. Setting the level of fees to be paid by Vendors, Subscribers, News Services or others for services relating to Quotation Information or Transaction Reports in Eligible Securities, and taking action in respect thereto in accordance with the provisions of the Plan;

4. Determining matters involving the interpretation of the provisions of the Plan;

5. Determining matters relating to the Plan's provisions for cost allocation and revenue-sharing; and

6. Carrying out such other specific responsibilities as provided under the Plan.

C. Operating Committee: Voting

Each Participant shall have one vote on all matters considered by the Operating Committee.

1. The affirmative and unanimous vote of all Participants entitled to vote shall be necessary to constitute the action of the Operating Committee with respect to:

a. Amendments to the Plan;

b. Amendments to contracts between the Processor and Vendors, Subscribers, News Services and others receiving Quotation Information and Transaction Reports in Eligible Securities;

c. Replacement of the Processor, except for termination for cause, which shall be governed by section V(B) hereof;

d. Reductions in existing fees relating to Quotation Information and Transaction Reports in Eligible Securities; and

e. Except as provided under Section IV(C)(3) hereof, requests for system changes; and

f. All other matters not specifically addressed by the Plan.

2. With respect to the establishment of new fees or increases in existing fees relating to Quotation Information and Transaction Reports in Eligible Securities, the affirmative vote of two-thirds of the Participants entitled to vote shall be necessary to constitute the action of the Operating Committee.

3. The affirmative vote of a majority of the Participants entitled to vote shall be necessary to constitute the action of the Operating Committee with respect to:

a. Requests for system changes reasonably related to the function of the Processor as defined under the Plan. All other requests for system changes shall be governed by Section IV(C)(1)(e) hereof.

b. Interpretive matters and decisions of the Operating Committee arising under, or specifically required to be taken by, the provisions of the Plan as written;

c. Interpretive matters arising under Exchange Act Rules 11Aa3–1 and 11Ac1–1; and

d. Denials of access (other than for breach of contract, which shall be handled by the Processor),

4. It is expressly agreed and understood that neither this Plan nor the Operating Committee shall have authority in any respect over any Participant's proprietary systems. Nor shall the Plan or the Operating Committee have any authority over the collection and dissemination of quotation or transaction information in Eligible Securities in any Participant's marketplace, or, in the case of the NASD, from NASD Participants.

D. Operating Committee: Meetings

Regular meetings of the Operating Committee may be attended by each Participant's designated representative and/or its alternate representative(s), and may be attended by one or more other representatives of the parties. Meetings shall be held at such times and locations as shall from time to time be determined by the Operating Committee.

Quorum: Any action requiring a vote only can be taken at a meeting in which a quorum of all Participants is present. For actions requiring a simple majority vote of all Participants, a quorum of greater than 50% of all Participants entitled to vote must be present at the meeting before such a vote may be taken. For actions requiring a ⅔ majority vote of all Participants, a

quorum of at least ⅔ of all Participants entitled to vote must be present at the meeting before such a vote may be taken. For actions requiring a unanimous vote of all Participants, a quorum of all Participants entitled to vote must be present at the meeting before such a vote may be taken.

A Participant is considered present at a meeting only if a Participant's designated representative or alternate representative(s) is either in physical attendance at the meeting or is participating by conference telephone, or other acceptable electronic means.

Any action sought to be resolved at a meeting must be sent to each Participant entitled to vote on such matter at least one week prior to the meeting via electronic mail, regular U.S. or private mail, or facsimile transmission, provided however that this requirement may be waived by the vote of the percentage of the Committee required to vote on any particular matter, under section C above.

Any action may be taken without a meeting if a consent in writing, setting forth the action so taken, is sent to and signed by all Participant representatives entitled to vote with respect to the subject matter thereof. All the approvals evidencing the consent shall be delivered to the Chairman of the Operating Committee to be filed in the Operating Committee records. The action taken shall be effective when the minimum number of Participants entitled to vote have approved the action, unless the consent specifies a different effective date.

The Chairman of the Operating Committee shall be elected annually by and from among the Participants by a majority vote of all Participants entitled to vote. The Chairman shall designate a person to act as Secretary to record the minutes of each meeting. The location of meetings shall be rotated among the locations of the principal offices of the Participants, or such other locations as may from time to time be determined by the Operating Committee. Meetings may be held by conference telephone and action may be taken without a meeting if the representatives of all Participants entitled to vote consent thereto in writing or other means the Operating Committee deems acceptable.

E. Advisory Committee

1. Composition

a. Each Plan Participant may designate three representatives to participate in the Advisory Committee. The representatives shall each be an employee of a member of that Participant, a professor or other academic involved in the scholarly study of the securities industry, or an expert in one or more areas of the securities industry.

b. Each representative shall serve a one-year term on the Advisory Committee.

2. Authority

The Advisory Committee shall have the opportunity to:

a. Meet twice yearly, each meeting to occur one day prior to a meeting of the Operating Committee.

b. Discuss any matter related to the operation of the Plan.

c. Present written comments or inquiries to the Operating Committee regarding matters related to the operation of the Plan.

d. Respond to written inquiries from the Operating Committee seeking comment from the Advisory Committee on matters related to the operation of the Plan.

V. Selection and Evaluation of the Processor

A. Generally

The Processor's performance of its functions under the Plan shall be subject to review by the Operating Committee at least every two years, or from time to time upon the request of any two Participants but not more frequently than once each year. Based on this review, the Operating Committee may choose to make a recommendation to the Participants with respect to the continuing operation of the Processor. The Operating Committee shall notify the SEC of any recommendations the Operating Committee shall make pursuant to the Operating Committee's review of the Processor and shall supply the Commission with a copy of any reports that may be prepared in connection therewith.

B. Termination of the Processor for Cause

If the Operating Committee determines that the Processor has failed to perform its functions in a reasonably acceptable manner in accordance with the provisions of the Plan or that its reimbursable expenses have become excessive and are not justified on a cost basis, the Processor may be terminated at such time as may be determined by a majority vote of the Operating Committee.

C. Factors To Be Considered in Termination for Cause

Among the factors to be considered in evaluating whether the Processor has performed its functions in a reasonably acceptable manner in accordance with the provisions of the Plan shall be the reasonableness of its response to requests from Participants for technological changes or enhancements pursuant to section IV(C)(3) hereof. The reasonableness of the Processor's response to such requests shall be evaluated by the Operating Committee in terms of the cost to the Processor of purchasing the same service from a third party and integrating such service into the Processor's existing systems and operations as well as the extent to which the requested change would adversely impact the then current technical (as opposed to business or competitive) operations of the Processor.

D. Processor's Right To Appeal Termination for Cause

The Processor shall have the right to appeal to the SEC a determination of the Operating Committee terminating the Processor for cause and no action shall become final until the SEC has ruled on the matter and all legal appeals of right therefrom have been exhausted.

E. Process for Selecting New Processor

At any time following effectiveness of the Plan, but no later than upon the termination of the Processor, whether for cause pursuant to section IV(C)(1)(c) or V(B) of the Plan or upon the Processor's resignation, the Operating Committee shall establish procedures for selecting a new Processor (the ''Selection Procedures''). The Operating Committee, as part of the process of establishing Selection Procedures, may solicit and consider the timely comment of any entity affected by the operation of this Plan. The Selection Procedures shall be established by a two-thirds majority vote of the Plan Participants, and shall set forth, at a minimum:

1. The entity that will:

(a) Draft the Operating Committee's request for proposal for bids on a new processor;

(b) Assist the Operating Committee in evaluating bids for the new processor; and

(c) Otherwise provide assistance and guidance to the Operating Committee in the selection process.

2. The minimum technical and operational requirements to be fulfilled by the Processor;

3. The criteria to be considered in selecting the Processor; and

4. The entities (other than Plan Participants) that are eligible to comment on the selection of the Processor.

Nothing in this provision shall be interpreted as limiting Participants'

rights under section IV or section V of the Plan or other Commission order.

VI. Functions of the Processor

A. Generally

The Processor shall collect from the Participants, and consolidate and disseminate to Vendors, Subscribers and News Services, Quotation Information and Transaction Reports in Eligible Securities in a manner designed to assure the prompt, accurate and reliable collection, processing and dissemination of information with respect to all Eligible Securities in a fair and non-discriminatory manner. The Processor shall commence operations upon the Processor's notification to the Participants that it is ready and able to commence such operations.

B. Collection and Consolidation of Information

For as long as Nasdaq is the Processor, the Processor shall be capable of receiving Quotation Information and Transaction Reports in Eligible Securities from Participants by the Plan-approved, Processor sponsored interface, and shall consolidate and disseminate such information via the UTP Quote Data Feed, the UTP Trade Data Feed, and the OTC Montage Data Feed to Vendors, Subscribers and News Services. For so long as Nasdaq is not registered as a national securities exchange and for so long as Nasdaq is the Processor, the Processor shall also collect, consolidate, and disseminate the quotation information contained in NQDS. For so long as Nasdaq is not registered as a national securities exchange and after Nasdaq is no longer the Processor for other SIP datafeeds, either Nasdaq or a third party will act as the Processor to collect, consolidate, and disseminate the quotation information contained in NQDS.

C. Dissemination of Information

The Processor shall disseminate consolidated Quotation Information and Transaction Reports in Eligible Securities via the UTP Quote Data Feed, the UTP Trade Data Feed, and the OTC Montage Data Feed to authorized Vendors, Subscribers and News Services in a fair and non-discriminatory manner. The Processor shall specifically be permitted to enter into agreements with Vendors, Subscribers and News Services for the dissemination of quotation or transaction information on Eligible Securities to foreign (non-U.S.) marketplaces or in foreign countries.

The Processor shall, in such instance, disseminate consolidated quotation or transaction information on Eligible Securities from all Participants.

Nothing herein shall be construed so as to prohibit or restrict in any way the right of any Participant to distribute quotation, transaction or other information with respect to Eligible Securities quoted on or traded in its marketplace to a marketplace outside the United States solely for the purpose of supporting an intermarket linkage, or to distribute information within its own marketplace concerning Eligible Securities in accordance with its own format. If a Participant requests, the Processor shall make information about Eligible Securities in the Participant's marketplace available to a foreign marketplace on behalf of the requesting Participant, in which event the cost shall be borne by that Participant.

1. Best Bid and Offer

The Processor shall disseminate on the UTP Quote Data Feed the best bid and offer information supplied by each Participant, including the Nasdaq market participants, and shall also calculate and disseminate on the UTP Quote Data Feed a national best bid and asked quotation with size based upon Quotation Information for Eligible Securities received from Participants. The Processor shall not calculate the best bid and offer for any individual Participant, including the NASD.

The Participant responsible for each side of the best bid and asked quotation making up the national best bid and offer shall be identified by an appropriate symbol. If the quotations of more than one Participant shall be the same best price, the largest displayed size among those shall be deemed to be the best. If the quotations of more than one Participant are the same best price and best displayed size, the earliest among those measured by the time reported shall be deemed to be the best. A reduction of only bid size and/or ask size will not change the time priority of a Participant's quote for the purposes of determining time reported, whereas an increase of the bid size and/or ask size will result in a new time reported. The consolidated size shall be the size of the Participant that is at the best.

If the best bid/best offer results in a locked or crossed quotation, the Processor shall forward that locked or crossed quote on the appropriate output lines (*i.e.*, a crossed quote of bid 12, ask 11.87 shall be disseminated). The Processor shall normally cease the calculation of the best bid/best offer after 6:30 p.m., Eastern Time.

2. Quotation Data Streams

The Processor shall disseminate on the UTP Quote Data Feed a data stream of all Quotation Information regarding Eligible Securities received from Participants. Each quotation shall be designated with a symbol identifying the Participant from which the quotation emanates. Quotation Information from individual NASD Participants will not be disseminated on the UTP Quote Data Feed. The Processor shall separately distribute on the OTC Montage Data Feed the Quotation Information regarding Eligible Securities from all NASD Participants from which quotations emanate. The Processor shall separately distribute NQDS for so long as Nasdaq is not registered as a national securities exchange and for so long as Nasdaq is the Processor. For so long as Nasdaq is not registered as a national securities exchange and after Nasdaq is no longer the Processor for other SIP datafeeds, either Nasdaq or a third party will act as the Processor to collect, consolidate, and disseminate the quotation information contained in NQDS.

3. Transaction Reports

The Processor shall disseminate on the UTP Trade Data Feed a data stream of all Transaction Reports in Eligible Securities received from Participants. Each transaction report shall be designated with a symbol identifying the Participant in whose Market the transaction took place.

D. Closing Reports

At the conclusion of each trading day, the Processor shall disseminate a ''closing price'' for each Eligible Security. Such ''closing price'' shall be the price of the last Transaction Report in such security received prior to dissemination. The Processor shall also tabulate and disseminate at the conclusion of each trading day the aggregate volume reflected by all Transaction Reports in Eligible Securities reported by the Participants.

E. Statistics

The Processor shall maintain quarterly, semi-annual and annual transaction and volume statistical counts. The Processor shall, at cost to the user Participant(s), make such statistics available in a form agreed upon by the Operating Committee, such as a secure website.

VII. Administrative Functions of the Processor

Subject to the general direction of the Operating Committee, the Processor shall be responsible for carrying out all

administrative functions necessary to the operation and maintenance of the consolidated information collection and dissemination system provided for in this Plan, including, but not limited to, record keeping, billing, contract administration, and the preparation of financial reports.

VIII. Transmission of Information to Processor by Participants

A. Quotation Information

Each Participant shall, during the time it is open for trading be responsible promptly to collect and transmit to the Processor accurate Quotation information in Eligible Securities through any means prescribed herein.

Quotation Information shall include:

1. Identification of the Eligible Security, using the Nasdaq Symbol;
2. The price bid and offered, together with size;
3. The Nasdaq market participant or Participant from which the quotation emanates;
4. Identification of quotations that are not firm; and
5. Through appropriate codes and messages, withdrawals and similar matters.

B. Transaction Reports

Each Participant shall, during the time it is open for trading, be responsible promptly to collect and transmit to the Processor Transaction Reports in Eligible Securities executed in its Market by means prescribed herein. With respect to orders sent by one Participant Market to another Participant Market for execution, each Participant shall adopt procedures governing the reporting of transactions in Eligible Securities specifying that the transaction will be reported by the Participant whose member sold the security. This provision shall apply only to transactions between Plan Participants.

Transaction Reports shall include:

1. Identification of the Eligible Security, using the Nasdaq Symbol;
2. The number of shares in the transaction;
3. The price at which the shares were purchased or sold;
4. The buy/sell/cross indicator;
5. The Market of execution; and,
6. Through appropriate codes and messages, late or out-of-sequence trades, corrections and similar matters.

All such Transaction Reports shall be transmitted to the Processor within 90 seconds after the time of execution of the transaction. Transaction Reports transmitted beyond the 90-second period shall be designated as ''late'' by the appropriate code or message.

The following types of transactions are not required to be reported to the Processor pursuant to the Plan:

1. Transactions that are part of a primary distribution by an issuer or of a registered secondary distribution or of an unregistered secondary distribution;
2. Transactions made in reliance on section 4(2) of the Securities Act of 1933;
3. Transactions in which the buyer and the seller have agreed to trade at a price unrelated to the Current Market for the security, *e.g.*, to enable the seller to make a gift;
4. Odd-lot transactions;
5. The acquisition of securities by a broker-dealer as principal in anticipation of making an immediate exchange distribution or exchange offering on an exchange;
6. Purchases of securities pursuant to a tender offer; and
7. Purchases or sales of securities effected upon the exercise of an option pursuant to the terms thereof or the exercise of any other right to acquire securities at a pre-established consideration unrelated to the Current Market.

C. Symbols for Market Identification for Quotation Information and Transaction Reports

The following symbols shall be used to denote the marketplaces:

Code	Participant
A	American Stock Exchange, LLC.
B	Boston Stock Exchange, Inc.
W	Chicago Board Options Exchange, Inc.
M	Chicago Stock Exchange, Inc.
D	National Association of Securities Dealers, Inc.
Q	Nasdaq Stock Market.
C	National Stock Exchange.
P	Pacific Exchange, Inc.
X	Philadelphia Stock Exchange, Inc.

D. Whenever a Participant determines that a level of trading activity or other unusual market conditions prevent it from collecting and transmitting Quotation Information or Transaction Reports to the Processor, or where a trading halt or suspension in an Eligible Security is in effect in its Market, the Participant shall promptly notify the Processor of such condition or event and shall resume collecting and transmitting Quotation Information and Transaction Reports to it as soon as the condition or event is terminated. In the event of a system malfunction resulting in the inability of a Participant or its members to transmit Quotation Information or Transaction Reports to the Processor, the Participant shall promptly notify the Processor of such event or condition. Upon receiving such notification, the Processor shall take appropriate action, including either closing the quotation or purging the system of the affected quotations.

IX. Market Access

A. Each Participant shall permit each Nasdaq market participant, acting in its capacity as such, direct telephone access to the specialist, trading post, and supervisory center in each Eligible Security in which such Nasdaq market participant is registered as a market maker or electronic communications network/alternative trading system with Nasdaq. Such access shall include appropriate procedures or requirements by each Participant or employee to assure the timely response to communications received through telephonic access. No Participant shall permit the imposition of any access or execution fee, or any other fee or charge, with respect to transactions in Eligible Securities effected with Nasdaq market participants which are communicated to the floor by telephone pursuant to the provisions of this Plan. A Participant shall be free to charge for other types of access to its floor or facilities.

B. The NASD shall assure that each Participant, and its members shall have direct telephone access to the trading desk of each Nasdaq market participant in each Eligible Security in which the Participant displays quotations, and to the Nasdaq Supervisory Center. Such access shall include appropriate procedures or requirements to assure the timely response of each Nasdaq market participant to communications received through telephone access. Neither the NASD nor any Nasdaq market participant shall impose any access or execution fee, or any other fee or charge, with respect to transactions in Eligible Securities effected with a member of a Participant which are communicated by telephone pursuant to the provisions of this Plan.

X. Regulatory Halts

A. For purposes of this section X, ''Participant'' shall include the Nasdaq Stock Market. Whenever, in the exercise of its regulatory functions, the Listing Market for an Eligible Security determines that a Regulatory Halt is appropriate pursuant to section III.T, the Listing Market will notify all other Participants pursuant to section X.E and all other Participants shall also halt or suspend trading in that security until notification that the halt or suspension is no longer in effect. The Listing Market shall immediately notify the Processor of such Regulatory Halt as well as notice

of the lifting of a Regulatory Halt. The Processor, in turn, shall disseminate to Participants notice of the Regulatory Halt (as well as notice of the lifting of a regulatory halt) through the UTP Quote Data Feed. This notice shall serve as official notice of a regulatory halt for purposes of the Plan only, and shall not substitute or otherwise supplant notice that a Participant may recognize or require under its own rules. Nothing in this provision shall be read so as to supplant or be inconsistent with a Participant's own rules on trade halts, which rules apply to the Participant's own members. The Processor will reject any quotation information or transaction reports received from any Participant on an Eligible Security that has a Regulatory Halt in effect.

B. Whenever the Listing Market determines that an adequate publication or dissemination of information has occurred so as to permit the termination of the Regulatory Halt then in effect, the Listing Market shall promptly notify the Processor and each of the other Participants that conducts trading in such security pursuant to section X.F. Except in extraordinary circumstances, adequate publication or dissemination shall be presumed by the Listing Market to have occurred upon the expiration of one hour after initial publication in a national news dissemination service of the information that gave rise to the Regulatory Halt.

C. Except in the case of a Regulatory Halt, the Processor shall not cease the dissemination of quotation or transaction information regarding any Eligible Security. In particular, it shall not cease dissemination of such information because of a delayed opening, imbalance of orders or other market-related problems involving such security. During a regulatory halt, the Processor shall collect and disseminate Transaction Information but shall cease collection and dissemination of all Quotation Information.

D. For purposes of this section X, ''Listing Market'' for an Eligible Security means the Participant's Market on which the Eligible Security is listed. If an Eligible Security is dually listed, Listing Market shall mean the Participant's Market on which the Eligible Security is listed that also has the highest number of the average of the reported transactions and reported share volume for the preceding 12-month period. The Listing Market for dually-listed Eligible Securities shall be determined at the beginning of each calendar quarter.

E. For purposes of coordinating trading halts in Eligible Securities, all Participants are required to utilize the national market system communication media (''Hoot-n-Holler'') to verbally provide real-time information to all Participants. Each Participant shall be required to continuously monitor the Hoot-n-Holler system during market hours, and the failure of a Participant to do so at any time shall not prevent the Listing Market from initiating a Regulatory Halt in accordance with the procedures specified herein.

1. The following procedures shall be followed when one or more Participants experiences extraordinary market activity in an Eligible Security that is believed to be caused by the misuse or malfunction of systems operated by or linked to one or more Participants.

a. The Participant(s) experiencing the extraordinary market activity or any Participant that becomes aware of extraordinary market activity will immediately use best efforts to notify all Participants of the extraordinary market activity utilizing the Hoot-n-Holler system.

b. The Listing Market will use best efforts to determine whether there is material news regarding the Eligible Security. If the Listing Market determines that there is non-disclosed material news, it will immediately call a Regulatory Halt pursuant to section X.E.2.

c. Each Participant(s) will use best efforts to determine whether one of its systems, or the system of a direct or indirect participant in its market, is responsible for the extraordinary market activity.

d. If a Participant determines the potential source of extraordinary market activity pursuant to section X.1.c., the Participant will use best efforts to determine whether removing the quotations of one or more direct or indirect market participants or barring one or more direct or indirect market participants from entering orders will resolve the extraordinary market activity. Accordingly, the Participant will prevent the quotations from one or more direct or indirect market participants in the affected Eligible Securities from being transmitted to the Processor.

e. If the procedures described in section X.E.1.a–d. do not rectify the situation, the Participant(s) experiencing extraordinary market activity will cease transmitting all quotations in the affected Eligible Securities to the Processor.

f. If the procedures described in section X.E.1.a–e do not rectify the situation within five minutes of the first notification through the Hoot-n-Holler system, or if Participants agree to call a halt sooner through unanimous approval among those Participants actively trading impacted Eligible Securities, the Listing Market may determine based on the facts and circumstances, including available input from Participants, to declare an Extraordinary Market Regulatory Halt in the affected Eligible Securities. Simultaneously with the notification of the Processor to suspend the dissemination of quotations across all Participants, the Listing Market must verbally notify all Participants of the trading halt utilizing the Hoot-n-Holler system.

g. Absent any evidence of system misuse or malfunction, best efforts will be used to ensure that trading is not halted across all Participants.

2. If the Listing Market declares a Regulatory Halt in circumstances other than pursuant to section X.E.1.f., the Listing Market must, simultaneously with the notification of the Processor to suspend the dissemination of quotations across all Participants, verbally notify all Participants of the trading halt utilizing the Hoot-n-Holler system.

F. If the Listing Market declares a Regulatory Halt, trading will resume according to the following procedures:

1. Within 15 minutes of the declaration of the halt, all Participants will make best efforts to indicate via the Hoot-n-Holler their intentions with respect to canceling or modifying transactions.

2. All Participants will disseminate to their members information regarding the canceled or modified transactions as promptly as possible, and in any event prior to the resumption of trading.

3. After all Participants have met the requirements of section X.F.1–2, the Listing Market will notify the Participants utilizing the Hoot-n-Holler and the Processor when trading may resume. Upon receiving this information, Participants may commence trading pursuant to section X.A.

XI. Hours of Operation

A. Quotation Information may be entered by Participants as to all Eligible Securities in which they make a market between 9:30 a.m. and 4 p.m. Eastern Time (''ET'') on all days the Processor is in operation. Transaction Reports shall be entered between 9:30 a.m. and 4:01:30 p.m. ET by Participants as to all Eligible Securities in which they execute transactions between 9:30 a.m. and 4 p.m. ET on all days the Processor is in operation.

B. Participants that execute transactions in Eligible Securities outside the hours of 9:30 a.m. ET and

4 p.m., ET, shall be required to report such transactions as follows:

(i) Transactions in Eligible Securities executed between 4 a.m. and 9:29:59 a.m. ET and between 4:00:01 and 6:30 p.m. ET, shall be designated as ''.T'' trades to denote their execution outside normal market hours;

(ii) Transactions in Eligible Securities executed after 6:30 p.m. and before 12 a.m. (midnight) shall be reported to the Processor between the hours of 4 a.m. and 6:30 p.m. ET on the next business day (T+1), and shall be designated ''as/of'' trades to denote their execution on a prior day, and be accompanied by the time of execution;

(iii) Transactions in Eligible Securities executed between 12 a.m. (midnight) and 4 a.m. ET shall be transmitted to the Processor between 4 a.m. and 9:30 a.m. ET, on trade date, shall be designated as ''.T'' trades to denote their execution outside normal market hours, and shall be accompanied by the time of execution;

(iv) Transactions reported pursuant to this provision of the Plan shall be included in the calculation of total trade volume for purposes of determining net distributable operating revenue, but shall not be included in the calculation of the daily high, low, or last sale.

C. Late trades shall be reported in accordance with the rules of the Participant in whose Market the transaction occurred and can be reported between the hours of 4 a.m. and 6:30 p.m.

D. The Processor shall collect, process and disseminate Quotation Information in Eligible Securities at other times between 4 a.m. and 9:30 a.m. ET, and after 4 p.m. ET, when any Participant or Nasdaq market participant is open for trading, until 6:30 p.m. ET (the ''Additional Period''); provided, however, that the best bid and offer quotation will not be disseminated before 4 a.m. or after 6:30 p.m. ET. Participants that enter Quotation Information or submit Transaction Reports to the Processor during the Additional Period shall do so for all Eligible Securities in which they enter quotations.

XII. Undertaking by All Participants

The filing with and approval by the Commission of this Plan shall obligate each Participant to enforce compliance by its members with the provisions thereof. In all other respects not inconsistent herewith, the rules of each Participant shall apply to the actions of its members in effecting, reporting, honoring and settling transactions executed through its facilities, and the entry, maintenance and firmness of quotations to ensure that such occurs in a manner consistent with just and equitable principles of trade.

XIII. Financial Matters

A. Development Costs

Any Participant becoming a signatory to this Plan after June 26, 1990, shall, as a condition to becoming a Participant, pay to the other Plan Participants a proportionate share of the aggregate development costs previously paid by Plan Participants to the Processor, which aggregate development costs totaled $439,530, with the result that each Participant's share of all development costs is the same.

Each Participant shall bear the cost of implementation of any technical enhancements to the Nasdaq system made at its request and solely for its use, subject to reapportionment should any other Participant subsequently make use of the enhancement, or the development thereof.

B. Cost Allocation and Revenue Sharing

The provisions governing cost allocation and revenue sharing among the Participants are set forth in Exhibit 1 to the Plan.

C. Maintenance of Financial Records

The Processor shall maintain records of revenues generated and development and operating expenditures incurred in connection with the Plan. In addition, the Processor shall provide the Participants with: (a) A statement of financial and operational condition on a quarterly basis; and (b) an audited statement of financial and operational condition on an annual basis.

XIV. Indemnification

Each Participant agrees, severally and not jointly, to indemnify and hold harmless each other Participant, Nasdaq, and each of its directors, officers, employees and agents (including the Operating Committee and its employees and agents) from and against any and all loss, liability, claim, damage and expense whatsoever incurred or threatened against such persons as a result of any Transaction Reports, Quotation Information or other information reported to the Processor by such Participant and disseminated by the Processor to Vendors. This indemnity agreement shall be in addition to any liability that the indemnifying Participant may otherwise have. Promptly after receipt by an indemnified Participant of notice of the commencement of any action, such indemnified Participant will, if a claim in respect thereof is to be made against an indemnifying Participant, notify the indemnifying Participant in writing of the commencement thereof; but the omission to so notify the indemnifying Participant will not relieve the indemnifying Participant from any liability which it may have to any indemnified Participant. In case any such action is brought against any indemnified Participant and it promptly notifies an indemnifying Participant of the commencement thereof, the indemnifying Participant will be entitled to participate in, and, to the extent that it may wish, jointly with any other indemnifying Participant similarly notified, to assume and control the defense thereof with counsel chosen by it. After notice from the indemnifying Participant of its election to assume the defense thereof, the indemnifying Participant will not be liable to such indemnified Participant for any legal or other expenses subsequently incurred by such indemnified Participant in connection with the defense thereof but the indemnified Participant may, at its own expense, participate in such defense by counsel chosen by it without, however, impairing the indemnifying Participant's control of the defense. The indemnifying Participant may negotiate a compromise or settlement of any such action, provided that such compromise or settlement does not require a contribution by the indemnified Participant.

XV. Withdrawal

Any Participant may withdraw from the Plan at any time on not less than 30 days prior written notice to each of the other Participants. Any Participant withdrawing from the Plan shall remain liable for, and shall pay upon demand, any fees for equipment or services being provided to such Participant pursuant to the contract executed by it or an agreement or schedule of fees covering such then in effect.

A withdrawing Participant shall also remain liable for its proportionate share, without any right of recovery, of administrative and operating expenses, including start-up costs and other sums for which it may be responsible pursuant to section XIV hereof. Except as aforesaid, a withdrawing Participant shall have no further obligation under the Plan or to any of the other Participants with respect to the period following the effectiveness of its withdrawal.

XVI. Modifications to Plan

The Plan may be modified from time to time when authorized by the agreement of all of the Participants, subject to the approval of the SEC.

XVII. Applicability of Securities Exchange Act of 1934

The rights and obligations of the Participants and of Vendors, News Services, Subscribers and other persons contracting with Participant in respect of the matters covered by the Plan shall at all times be subject to any applicable provisions of the Act, as amended, and any rules and regulations promulgated thereunder.

XVIII. Operational Issues

A. Each Exchange Participant shall be responsible for collecting and validating quotes and last sale reports within their own system prior to transmitting this data to the Processor.

B. Each Exchange Participant may utilize a dedicated Participant line into the Processor to transmit trade and quote information in Eligible Securities to the Processor. The Processor shall accept from Exchange Participants input for only those issues that are deemed Eligible Securities.

C. The Processor shall consolidate trade and quote information from each Participant and disseminate this information on the Nasdaq existing vendor lines.

D. The Processor shall perform gross validation processing for quotes and last sale messages in addition to the collection and dissemination functions, as follows:

1. Basic Message Validation.

(a) The Processor may validate format for each type of message, and reject non-conforming messages.

(b) Input must be for an Eligible Security.

2. Logging Function—The Processor shall return all Participant input messages that do not pass the validation checks (described above) to the inputting Participant, on the entering Participant line, with an appropriate reject notation. For all accepted Participant input messages (i.e., those that pass the validation check), the information shall be retained in the Processor system.

XIX. Headings

The section and other headings contained in this Plan are for reference purposes only and shall not be deemed to be a part of this Plan or to affect the meaning or interpretation of any provisions of this Plan.

XX. Counterparts

This Plan may be executed by the Participants in any number of counterparts, no one of which need contain the signature of all Participants. As many such counterparts as shall together contain all such signatures shall constitute one and the same instrument.

XXI. Depth of Book Display

The Operating Committee has determined that the entity that succeeds Nasdaq as the Processor should have the ability to collect, consolidate, and disseminate quotations at multiple price levels beyond the best bid and best offer from any Participant that voluntarily chooses to submit such quotations while determining that no Participant shall be required to submit such information. The Operating Committee has further determined that the costs of developing, collecting, processing, and disseminating such depth of book data shall be borne exclusively by those Participants that choose to submit this information to the Processor, by whatever allocation those Participants may choose among themselves. The Operating Committee has determined further that the primary purpose of the Processor is the collection, processing and dissemination of best bid, best offer and last sale information (''core data''), and as such, the Participants will adopt procedures to ensure that such functionality in no way hinders the collecting, processing and dissemination of this core data.

Therefore, implementing the depth of book display functionality will require a plan amendment that addresses all pertinent issues, including:

(1) Procedures for ensuring that the fully-loaded cost of the collection, processing, and dissemination of depth-of-book information will be tracked and invoiced directly to those Plan Participants that voluntarily choose to send that data, voluntarily, to the Processor, allocating in whatever manner those Participants might agree; and

(2) Necessary safeguards the Processor will take to ensure that its processing of depth-of-book data will not impede or hamper, in any way, its core Processor functionality of collecting, consolidating, and disseminating National Best Bid and Offer data, exchange best bid and offer data, and consolidated last sale data.

Upon approval of a Plan amendment implementing depth of book display, this article of the Plan shall be automatically deleted.

In Witness Whereof, this Plan has been executed as of the_____ day of_____, 200__, by each of the Signatories hereto.

American Stock Exchange LLC
By:
Boston Stock Exchange, Inc.
By:
Chicago Stock Exchange, Inc.
By:
Chicago Board Options Exchange, Inc.
By:
International Securities Exchange, Inc.
By:
National Association of Securities Dealers, Inc.
By:
National Stock Exchange
By:
New York Stock Exchange, Inc.
By:
Pacific Exchange, Inc.
By:
Philadelphia Stock Exchange, Inc.
By:

Exhibit 1

1. Each Participant eligible to receive revenue under the Plan will receive an annual payment for each calendar year to be determined by multiplying (i) that Participant's percentage of total volume in Nasdaq securities reported to the Processor for that calendar year by (ii) the total distributable net operating income (as defined below) for that calendar year. In the event that total distributable net operating income is negative, each Participant eligible to receive revenue under the Plan will receive an annual bill for each calendar year to be determined according to the same formula (described in this paragraph) for determining annual payments to eligible Participants.

2. A Participant's percentage of total volume in Nasdaq securities will be calculated by taking the average of (i) the Participant's percentage of total trades in Nasdaq securities reported to the Processor for the year and (ii) the Participant's percentage of total share volume in Nasdaq securities reported to the Processor for the year (trade/volume average). For any given year, a Participant's percentage of total trades shall be calculated by dividing the total number of trades that that Participant reports to the Processor for that year by the total number of trades in Nasdaq securities reported to the Processor for the year. A Participant's total share volume shall be calculated by multiplying the total number of trades in Nasdaq securities in that year that that Participant reports to the Processor multiplied by the number of shares for each such trade. Unless otherwise stated in this agreement, a year shall run from January 1 to December 31 and quarters shall end on March 31, June 30, September 30, and December 31. Processor shall endeavor to provide Participants with written estimates of each Participant's percentage of total volume within five business days of month end.

3. For purposes of this Exhibit 1, net distributable operating income for any

particular calendar year shall be calculated by adding all revenues from the UTP Quote Data Feed, the UTP Trade Data Feed, the OTC Montage Data Feed, and NQDS, including revenues from the dissemination of information among Eligible Securities to foreign marketplaces (collectively, ''the Data Feeds''), and subtracting from such revenues the costs incurred by the Processor, set forth below, in collecting, consolidating, validating, generating, and disseminating the Data Feeds. These costs include, but are not limited to, the following:

a. The Processor costs directly attributable to creating OTC Montage Data Feed and NQDS, including:

1. Cost of collecting Participant quotes into the Processor's quote engine;

2. Cost of processing quotes and creating OTC Montage Data Feed and NQDS messages within the Processor's quote engine;

3. Cost of the Processor's communication management subsystem that distributes OTC Montage Data Feed and NQDS to the market data vendor network for further distribution.

b. The costs directly attributable to creating the UTP Quote Data Feed, including:

1. Cost of calculating the national best bid and offer price within the Processor's quote engine;

2. Cost of creating the UTP Quote Data Feed message within the Processor's quote engine;

3. Cost of the Processor's communication management subsystem that distributes the UTP Quote Data Feed to the market data vendors' networks for further distribution.

c. The costs directly attributable to creating the UTP Trade Data Feed, including:

1. Cost of determining the appropriate last sale price and volume amount within the Processor's trade engine;

2. Cost of utilizing the Processor's trade engine to distribute the UTP Trade Data Feed for distribution to the market data vendors.

d. The additional costs that are shared across all Data Feeds, including:

1. Telecommunication Operations costs of supporting the Participant lines into the Processor's facilities;

2. Telecommunications Operations costs of supporting the external market data vendor network;

3. Data Products account management and auditing function with the market data vendors;

4. Market Operations costs to support symbol maintenance, and other data integrity issues;

5. Overhead costs, including management support of the Processor, Human Resources, Finance, Legal, and Administrative Services.

e. Processor costs excluded from the calculation of net distributable operating income include trade execution costs for transactions executed using a Nasdaq service and trade report collection costs reported through a Nasdaq service, as such services are market functions for which Participants electing to use such services pay market rate.

f. For the purposes of this provision, the following definitions shall apply:

1. ''Quote engine'' shall mean the Nasdaq's NT or Tandem system that is operated by Nasdaq to collect quotation information for Eligible Securities;

2. ''Trade engine'' shall mean the Nasdaq Tandem system that is operated by Nasdaq for the purpose of collecting last sale information in Eligible Securities.

4. At the time a Participant implements a computer-to-computer-interface or other Processor-approved electronic interface with the Processor, the Participant will become eligible to receive revenue.

5. Processor shall endeavor to provide Participants with written estimates of each Participant's quarterly net distributable operating income within 45 calendar days of the end of the quarter, and estimated quarterly payments or billings shall be made on the basis of such estimates. All quarterly payments or billings shall be made to each eligible Participant within 45 days following the end of each calendar quarter in which the Participant is eligible to receive revenue, provided that each quarterly payment or billing shall be reconciled against a Participant's cumulative year-to-date payment or billing received to date and adjusted accordingly, and further provided that the total of such estimated payments or billings shall be reconciled at the end of each calendar year and, if necessary, adjusted by March 31st of the following year. Interest shall be included in quarterly payments and in adjusted payments made on March 31st of the following year. Such interest shall accrue monthly during the period in which revenue was earned and not yet paid and will be based on the 90-day Treasury bill rate in effect at the end of the quarter in which the payment is made. Monthly interest shall start accruing 45 days following the month in which it is earned and accrue until the date on which the payment is made.

In conjunction with calculating estimated quarterly and reconciled annual payments under this Exhibit 1, the Processor shall submit to the Participants a quarterly itemized statement setting forth the basis upon which net operating income was calculated, including a quarterly itemized statement of the Processor costs set forth in Paragraph 3 of this Exhibit. Such Processor costs and Plan revenues shall be adjusted annually based solely on the Processor's quarterly itemized statement audited pursuant to Processor's annual audit. Processor shall pay or bill Participants for the audit adjustments within thirty days of completion of the annual audit. By majority vote of the Operating Committee, the Processor shall engage an independent auditor to audit the Processor's costs or other calculation(s), the cost of which audit shall be shared equally by all Participants. The Processor agrees to cooperate fully in providing the information necessary to complete such audit.

[FR Doc. E6–773 Filed 1–23–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meetings during the week of January 23, 2006: Closed Meetings will be held on Thursday, January 26, 2006 at 9 a.m. and on January 26, 2006 at 2 p.m.

Commissioners and certain staff members who have an interest in the matter will attend the Closed Meeting on January 26, 2006 at 9 a.m. Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting on January 26, 2006 at 2 p.m. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c), (3), (5), (7), (8), (9)(B), and (10) and 17 CFR 200.402(a), (3), (5), (7), (8), 9(ii) and (10) permit consideration of the scheduled matters at the Closed Meetings.

Commissioner Glassman, as duty officer, voted to consider the items listed for the closed meetings in closed sessions and that no earlier notice thereof was possible.

The subject matter of the Closed Meeting scheduled for 9 a.m. on Thursday, January 26, 2006 will be:

Institution and settlement of an injunctive action.

The subject matter of the Closed Meeting scheduled for 2 p.m. on Thursday, January 26, 2006 will be:

Formal orders of investigations;
Institution and settlement of injunctive actions;
Institution and settlement of administrative proceedings of an enforcement nature;
Opinion; and
Amici consideration.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 551–5400.

Dated: January 20, 2006.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 06–707 Filed 1–20–06; 12:52 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. PA–34; File No. S7–02–06]

Privacy Act of 1974: Establishment of a New System of Records: Visitor Badge and Employee Day Pass System (SEC–52)

AGENCY: Securities and Exchange Commission.

ACTION: Notice of the establishment of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Securities and Exchange Commission gives notice of a proposed Privacy Act system of records: ''Visitor Badge and Employee Day Pass System (SEC–52).'' This system of records will contain, among other things, records of Commission visitors, employee day pass information and records related to the status of trackable (special handling) mail.

DATES: The new system will become effective March 6, 2006 unless further notice is given. The Commission will publish a new notice if the effective date is delayed to review comments or if changes are made based on comment received. To be assured of consideration, comments should be received on or before February 23, 2006.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/other.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number S7–02–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number S7–02–06. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/other.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Barbara A. Stance, Chief Privacy Officer, U.S. Securities and Exchange Commission, Operations Center, 6432 General Green Way, Alexandria, VA 22312–2413, (202) 551–7209.

SUPPLEMENTARY INFORMATION: The Commission gives notice of the proposed establishment of a new system of records, entitled ''Visitor Badge and Employee Day Pass System (SEC–52).'' The new system will contain records of Commission visitors, employee day pass information and records related to the status of trackable (special handling) mail.

The Commission has submitted a report of the new system of records to the Senate Committee on Homeland Security and Governmental Affairs, the House Committee on Government Reform, and the Office of Management and Budget, pursuant to 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, and Appendix I to OMB Circular A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' as amended on February 20, 1996 (61 FR 6435).

Accordingly, the Commission is adding a new system of records to read as follows:

SEC–52

SYSTEM NAME:

Visitor Badge and Employee Day Pass System.

SYSTEM LOCATION:

U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Visitors from the public, other Federal agencies, Commission employees who require a Day Pass and Commission employees who pre-register or authorize visitors. The system also covers individuals or organizations that send and/or deliver trackable mail to the Commission (*e.g.*, express mail, courier mail, or other forms of mail that is tracked from the sender to the recipient).

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may include name, photograph, signature, company name, the number of the printed badge issued for each visit, visitor category, business phone number, fax number, address, e-mail address, Web site if available, other information from scanned business cards, and the location, date, and time of entry to the secure Commission facility. Records will also include the following information from scanned driver's licenses: Date of birth, weight, height, color of hair and eyes, date of expiration, and issuing jurisdiction (license numbers will not be saved in the system). Further information contained within the system will be the name and title of the person being visited, the reason for the visit to the facility, notation of approved parking, and the name, phone number and e-mail address of Commission personnel requesting authorization for the visitor access. The system will maintain check in and check out times, current status of visitor, and a custom ID number assigned sequentially by the system software for each visitor record. The software system and data base has a module for tracking packages as well. Records include package check in time, quantity of packages, name of employee to whom the package is addressed, location of package, sender's name, type of package, added description (if appropriate), carrier/agent delivering the package, time and name of person to whom package is delivered (final destination within the Commission), and a custom ID number assigned sequentially by the system software for each visitor record.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and Executive Order 13231 of October 16, 2001 on Critical Infrastructure Protection.

PURPOSE(S):

This system was primarily designed to permit access to Commission facilities by public visitors and representatives from other Federal agencies. It is also used to issue day passes for Commission staff members or contract employees who are not presently in possession of their ID and need to enter the workplace to perform their duties. The system is further used to record and monitor the status of trackable (special handling) mail.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

These records and information contained in these records may be disclosed as follows:

(1) To the appropriate Federal, State or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where the Commission or other appropriate Federal, State or local agency may be aware of an indication of an actual or potential health, safety or national security concern or a violation or potential violation of civil or criminal law or regulation;

(2) To another Federal agency, in connection with a court proceeding when the Government is party to a proceeding before the court or to an adjudicative tribunal when the Government is appearing in a proceeding before that tribunal;

(3) To a Federal, State, or local agency, in response to its requests, in connection with the hiring or retention of an employee, the issuance of a security clearance, or the conducting of a security or background investigation of an individual, to the extent that the information is relevant and necessary to the requesting agency;

(4) To the Office of the Inspector General for investigating allegations of abuse or misconduct, or to perform other functions within the jurisdiction of the Office of the Inspector General; and

(5) To the Commission Security Branch and/or the Office of the Inspector General in routine and ad hoc reports to review visitor and day pass activity and to assess compliance with established security procedures and policies.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in a computerized database and on paper. Paper documents are kept in filing cabinets in secured facilities.

RETRIEVABILITY:

By use of a database, records may be retrieved by the individual's name, date of visit and/or badge number (as printed in the form of a bar code on the badge).

SAFEGUARDS:

Records are safeguarded by restricted computer passwords, locked file cabinets, and safes.

RETENTION AND DISPOSAL:

Records are maintained in a computerized database and on paper. Printed badges, and returned passes (and corresponding electronic records) are destroyed three months after expiration, revocation, or return to issuing office, as provided in the National Archives and Records Administration's General Records Schedule No. 11, Item 4.

SYSTEM MANAGER(S) AND ADDRESS:

Chief of Security Branch, Office of Administrative Services, Security Branch, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1627.

NOTIFICATION PROCEDURE:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the Privacy Act Officer, U.S. Securities and Exchange Commission, Operations Center, 6432 General Green Way, Mail Stop 0–7, Alexandria, VA 22312–2413.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of this record may contact the Privacy Act Officer, U.S. Securities and Exchange Commission, Operations Center, 6432 General Green Way, Mail Stop 0–7, Alexandria, VA 22312–2413.

CONTESTING RECORDS PROCEDURES:

See record access procedures above.

RECORD SOURCE CATEGORIES:

Information is provided by the visitor seeking access to Commission facilities to meet with Commission employees or contractors, by Commission employees who pre-register visitors, and by Commission employees or badged contractors who do not have their ID and yet seek access to their workplace for official business. Additionally, information is provided by individuals sending trackable (special handling) mail. Information is further provided by carriers and/or agents that deliver such mail. Persons who decline to provide the requested information will be denied access.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Date: January 18, 2006.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E6–805 Filed 1–23–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53135; File No. SR–CBOE–2005–83]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Approving Proposed Rule Change Relating to the SizeQuote Mechanism

January 17, 2006.

On October 11, 2005, the Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to modify its pilot SizeQuote Mechanism for the execution of large-sized orders in open outcry.[3] The proposed rule change was published for comment in the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] CBOE Rule 6.74(f), which sets forth the rules and procedures for use of the SizeQuote Mechanism, was approved by the Commission in February 2005 for adoption on a pilot basis. *See* Securities Exchange Act Release No. 51205 (February 15, 2005), 70 FR 8647 (February 22, 2005).

In brief, a floor broker seeking to use the SizeQuote Mechanism to facilitate a customer's large-sized order (''SizeQuote Order) must request a ''SizeQuote'' from in-crowd market participants (''ICMPs''), who may respond with indications of the price and size at which they would be willing to trade with the order. ICMPs who respond at the best price have priority to trade with the order at that best price and at one trading increment better (the ''improved best price''). If the ICMPs do not execute the entire SizeQuote Order, the floor broker must be prepared to execute the remaining contracts against a facilitation order at the best price or the improved best price, as applicable. However, the floor broker has priority to facilitate the entire SizeQuote Order at a price two trading increments better than the best price provided by the ICMPs. For a more complete description, see Securities Exchange Act Release No. 50967 (January 5, 2005), 70 FR 2197 (January 12, 2005).

Federal Register on December 12, 2005.[4] The Commission received no comments regarding the proposal. This order approves the proposed rule change.

The proposed rule change would establish that, in addition to a floor broker crossing a SizeQuote Order with a facilitation order in accordance with the SizeQuote Mechanism's procedures, a floor broker also may cross the SizeQuote order with one or more solicited orders or a combination of solicited and facilitation orders.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b)(5) of the Act.[5] The Commission believes that, by giving floor brokers the alternative of crossing customers' SizeQuote Orders with solicited orders, the proposed rule change is intended to expand the potential benefits of the SizeQuote Mechanism. The Commission notes that the proposal does not alter the procedures a floor broker must follow in executing SizeQuote Orders.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[6] that the proposed rule change (SR–CBOE–2005–83) is approved until the expiration of the current SizeQuote pilot program on February 15, 2006.[7]

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E6–778 Filed 1–23–06; 8:45 am]

BILLING CODE 8010–01–P

[4] *See* Securities Exchange Act Release No. 52888 (December 5, 2005), 70 FR 73492.

[5] 15 U.S.C. 78f(b)(5). In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78s(b)(2).

[7] The Commission notes that the current SizeQuote pilot program expires on February 15, 2006. The Exchange has indicated to Commission staff its intent to propose an extension of the pilot program, as amended by the instant proposal, for an additional year. Telephone Conversation between Jennifer Lamie, Managing Senior Attorney, CBOE and Ira Brandriss, Special Counsel, Division of Market Regulation, Commission on January 13, 2006.

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53111; File No. SR–NASD–2006–002]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto Related to Non-NASD Member Broker-Dealer Access to Nasdaq's Brut Facility

January 12, 2006.

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 January 3, 2006, the National Association of Securities Dealers, Inc. (''NASD''), through its subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. On January 12, 2006, Nasdaq submitted Amendment No. 1 to the proposed rule change.[3] Nasdaq has filed the proposal pursuant to section 19(b)(3)(A) of the Act[4] and Rule 19b–4(f)(6) thereunder,[5] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to continue to provide, through February 8, 2006, broker-dealers that are not members of the NASD access to Nasdaq's Brut facility. Nasdaq states that it would implement the proposed rule change, as amended, immediately. Nasdaq has designated this proposal as non-controversial and has requested that the Commission waive the five-day pre-filing requirement and the 30-day pre-operative waiting period contained in Rule 19b–4(f)(6)(iii) under the Act.[6]

The text of the proposed rule change, as amended, is below. Proposed new language is *italicized;* proposed deletions are in [brackets].

* * * * *

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 made technical changes to the proposed rule change.

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(6).

[6] 17 CFR 240.19b–4(f)(6)(iii).

4901. Definitions

(a) through (h) No Change.

(i) The term ''Participant'' shall mean an NASD member that fulfills the obligations contained in Rule 4902 regarding participation in the System. Until [December 31, 2005,] *February 8, 2006,* the term ''Participant'' shall also include non-NASD [members] *broker/dealers* that desire to use the System and otherwise meet all other requirements for System participation.

(j) through (w) No Change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change, as amended, and discussed any comments it received on the proposed rule change, as amended. The text of these statements may be examined at the places specified in Item IV below. Nasdaq 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

Under current NASD Rule 4901(i), entities that are not members of the NASD may use the Brut system until December 31, 2005. Nasdaq proposes to amend this provision so as to allow non-NASD member broker-dealers to use the Brut system through February 8, 2006.[7] Nasdaq notes that the continued provision of such access impacts seven current Brut broker-dealer users (four active and three inactive), which Nasdaq believes is similar to access already being provided by the Arca Trading subsidiary of the Archipelago Exchange.[8] Nasdaq commits that Brut will not accept any new broker-dealer subscribers to its system that are non-NASD members during the extended

[7] Nasdaq states that non-NASD member entities that are not broker-dealers will not be able to use the Brut system beyond December 31, 2005. Nasdaq states that the February 8, 2006 date was selected to coincide with the current deadline for non-NASD member broker-dealers to leave Nasdaq's INET Facility. *See* Securities Exchange Act Release No. 52902 (December 7, 2005); 70 FR 73810 (December 13, 2005) (SR–NASD–2005–128). Nasdaq states that the INET Facility is expected to be merged into the Brut broker-dealer in the near future.

[8] *See* Securities Exchange Act Release No. 52497 (September 22, 2005); 70 FR 56949 (September 29, 2005) (SR–PCX–2005–90).

access period for current non-NASD member broker-dealer system users proposed in this filing.

2. Statutory Basis

Nasdaq believes that the proposed rule change, as amended, is consistent with the provisions of section 15A of the Act,[9] in general, and with section 15A(b)(6) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, and to remove impediments to a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change, as amended, will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change, as amended, is subject to section 19(b)(3)(A)(iii) of the Act [11] and Rule 19b–4(f)(6) thereunder [12] because the proposal: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative prior to 30 days after the date of filing or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest; provided that Nasdaq has given the Commission notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

Nasdaq has requested that the Commission waive the five-day pre-filing requirement and the 30-day operative delay. The Commission believes that waiving the five-day pre-filing requirement and the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver will permit current non-NASD member broker-dealers continued access to the Brut system without disruption. In addition, the Commission notes that the proposed rule's February 8, 2006 date matches the date for which non-NASD members are required to leave Nasdaq's INET facility. For these reasons, the Commission designates the proposed rule change, as amended, to be effective and operative upon filing with the Commission.[13]

At any time within 60 days of the filing of such proposed rule change, as amended, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Act.[14]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASD–2006–002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–NASD–2006–002. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change, as amended, that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of the NASD. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASD–2006–002 and should be submitted on or before February 14, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E6–777 Filed 1–23–06; 8:45 am]

BILLING CODE 8010–01–P

[9] 15 U.S.C. 78o–3.

[10] 15 U.S.C. 78o–3(b)(6).

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[14] The effective date of the original proposed rule change is January 3, 2006 and the effective date of Amendment No. 1 is January 12, 2006. For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change, as amended, under section 19(b)(3)(C) of the Act, the Commission considers the period to commence on January 12, 2006, the date on which the Exchange submitted Amendment No. 1. *See* 15 U.S.C. 78s(b)(3)(C).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53117; File No. SR–PCX–2005–87]

Self-Regulatory Organizations; Pacific Exchange, Inc.; Order Approving Proposed Rule Change, and Amendment No. 1 Thereto, Relating to the Tracking Order Process

January 13, 2006.

I. Introduction

On July 26, 2005, the Pacific Exchange, Inc. (''PCX'' or ''Exchange''), through its wholly-owned subsidiary PCX Equities, Inc. (''PCXE''), filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to replace the existing PCXE rules describing its current tracking order process (''Tracking Order Process'') [3] with new provisions for the Tracking Order Process. The PCX filed Amendment No. 1 to the proposed rule

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* PCXE Rule 7.37(c).

change on November 22, 2005.[4] The proposed rule change, as amended, was published for comment in the **Federal Register** on December 13, 2005.[5] The Commission received no comments on the proposed rule change, as amended.

II. Description

The PCX proposes to amend its rules governing the Archipelago Exchange (''ArcaEx''), the equities trading facility of PCXE. Specifically, the Exchange proposes to restructure its Tracking Order Process by modifying the current rule text governing the Tracking Order Process[6] to implement a process based on the submission of orders, rather than instructions, to be executed in price/time priority.[7]

PCX represents that the purpose of the Tracking Order Process is to provide a final opportunity for execution against any remaining liquidity on the ArcaEx system before routing to an away market center.[8] Under the proposed rule change, as is currently the case, if an order submitted to the ArcaEx has not been executed in its entirety after progressing through ArcaEx's directed order, display order and working order processes,[9] the order (or the remaining portion of the order) would enter the Tracking Order Process. An incoming order would be matched to Tracking Orders held in the Tracking Order Process based on the price and time the Tracking Order was received. Under the proposal, a ''Tracking Order'' is an undisplayed, priced round lot order that is eligible for execution in the Tracking Order Process against an order equal to or less than the aggregate size of Tracking Order interest available at that price.[10] Tracking Orders would execute only if the price of the Tracking Order is equal to or better than the national best bid or offer (''NBBO'').[11] Pursuant to the proposed rule change, odd lot orders would continue to be matched to odd lot tracking orders held in the Tracking Order Process in accordance with a user's[12] set parameters, such as maximum aggregate size, maximum tradeable size, and the price (which is set at the NBBO).[13]

III. Discussion

After careful review, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[14] In particular, the Commission finds that the proposal, as amended, is consistent with Section 6(b)(5) of the Act,[15] which requires, among other things, that a national securities exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and 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.

The Commission believes that under the proposal, incoming orders executed in the Tracking Order Process should be executed in a manner equivalent to that under PCX's existing rules, but that the proposed rule change should simplify the process for entering Tracking Orders. Thus, the Commission believes that the proposed changes to the Tracking Order Process do not raise any new issues or regulatory concerns. The Commission notes that an order may not be executed pursuant to the new Tracking Order Process at a price that is inferior to the NBBO.[16] Furthermore, the Commission notes that any order that is not executed in its entirety pursuant to one of ArcaEx's other order execution processes is eligible for matching and execution pursuant to the Tracking Order Process, and that any User of the ArcaEx system may submit a Tracking Order.[17]

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[18] that the proposed rule change (SR–PCX–2005–87), as amended by Amendment No.1, be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[19]

Nancy M. Morris,

Secretary.

[FR Doc. E6–772 Filed 1–23–06; 8:45 am]

BILLING CODE 8010–01–P

[4] Amendment No. 1, which replaced the original filing in its entirety, made technical and clarifying changes to the proposed rule change.

[5] *See* Exchange Act Release No. 52898 (Dec. 6, 2005), 70 FR 73811 (Dec. 13, 2005) (''Notice'').

[6] *See* PCXE Rule 7.37(c).

[7] *See* proposed PCXE Rule 7.31(f).

[8] *See* Notice.

[9] *See* PCXE Rule 7.37 for a description of the ArcaEx execution processes that precede the Tracking Order Process, including the directed process, display process, and working order process. *See also* proposed PCX Rule 7.37(c).

[10] *See* Proposed PCXE Rule 7.31(f).

[11] *See* PCXE Rule 7.37.

[12] ''User'' is defined in PCXE Rule 1.1(yy).

[13] *See* current and proposed PCXE Rule 7.31(g) for a definition of the odd lot tracking order and proposed PCXE Rule 7.37(c) for a description of the odd lot tracking order process.

[14] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78f(b)(5).

[16] *See* PCXE Rule 7.37.

[17] As is currently the case, only an ''Odd Lot Dealer,'' as defined in PCXE Rule 1.1(gg), may submit an odd lot tracking order. See current and proposed PCXE Rule 7.31(g).

[18] 15 U.S.C. 78s(b)(2).

[18] 15 U.S.C. 78s(b)(2).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 10316 and # 10317]

Oklahoma Disaster # OK–00002

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA–1623–DR), dated 01/10/2006 .

Incident: Severe Wildfire Threat.

Incident Period: 12/01/2005 and continuing.

Effective Date: 01/10/2006.

Physical Loan Application Deadline Date: 03/13/2006.

Economic Injury (EIDL) Loan Application Deadline Date: 10/10/2006.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, National Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 01/10/2006, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (physical damage and economic injury loans):

Canadian, Cotton, Garvin, Hughes, Lincoln, Logan, Mayes, Okfuskee, Oklahoma, Pottawatomie, Seminole, Stephens.

Contiguous Counties (Economic Injury Loans Only):

Oklahoma: Blaine, Caddo, Carter, Cherokee, Cleveland, Coal, Comanche, Craig, Creek, Delaware, Garfield, Grady, Jefferson, Kingfisher, Mcclain, Mcintosh,

Murray, Noble, Okmulgee, Payne, Pittsburg, Pontotoc, Rogers, Tillman, Wagoner.

Texas: Clay, Wichita.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	5.375
Homeowners without credit available elsewhere	2.687
Businesses with credit available elsewhere	6.557
Businesses and pon-profit organizations without credit available elsewhere	4.000
Other (including non-profit organizations) with credit available elsewhere	5.000
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 103165 and for economic injury is 103170.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E6–762 Filed 1–23–06; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #10314 and #10315]

Puerto Rico Disaster #PR–00001

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the Commonwealth of Puerto Rico dated January 10, 2006.

Incident: Severe Storm, Flooding and Mudslides.

Incident Period: October 9, 2005 through October 15, 2005.

Effective Date: January 10, 2006.

Physical Loan Application Deadline Date: March 13, 2006.

Economic Injury (EIDL) Loan Application Deadline Date: October 10, 2006.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, National Processing and Disbursement Center, 14925 Kingsport Road Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Municipalities:

Lares, Penuelas, Ponce, Toa Baja.

Contiguous Municipalities: Puerto Rico:

Adjuntas, Bayamon, Camuy, Catano, Dorado, Guayanilla, Hatillo, Jayuya, Juana Diaz, Las Marias, Maricao, San Sebastian, Toa Alta, Utuado, Yauco.

The Interest Rates are:

	Percent
Homeowners With Credit Available Elsewhere	5.375
Homeowners Without Credit Available Elsewhere	2.687
Businesses With Credit Available Elsewhere	6.557
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	4.750
Businesses And Non-Profit Organizations Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 10314 6 and for economic injury is 10315 0.

The States which received an EIDL Declaration # are Puerto Rico.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: January 10, 2006.

Hector V. Barreto,

Administrator.

[FR Doc. E6–759 Filed 1–23–06; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 10322 and # 10323]

Texas Disaster # TX–00097

AGENCY: U.S. Small Business Administration.

Administration Action: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Texas (FEMA–1624–DR), dated 01/11/2006.

Incident: Extreme Wildfire Threat.

Incident Period: 12/01/2005 and continuing.

Effective Date: 01/11/2006.

Physical Loan Application Deadline Date: 03/13/2006.

Economic Injury (EIDL) Loan Application Deadline Date: 10/11/2006.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, National Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 01/11/2006, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans):

Callahan, Cooke, Eastland, Erath, Hood, Montague, Palo, Pinto, Tarrant, Wise.

Contiguous Counties (Economic Injury Loans Only):

Texas: Bosque, Brown, Clay, Coleman, Comanche, Dallas, Denton, Ellis, Grayson, Hamilton, Jack, Johnson, Somervell, Stephens, Taylor, Young.

Oklahoma: Jefferson, Love.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	5.375
Homeowners without credit available elsewhere	2.687
Businesses with credit available elsewhere	6.557
Other (including non-profit organizations) with credit available elsewhere	5.000
Businesses and non-profit organizations without credit available elsewhere	4.000
For Economic Injury:	
Businesses & small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 103225 and for economic injury is 103230.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E6–761 Filed 1–23–06; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Agreement on Social Security Between the United States and Japan; Entry Into Force

AGENCY: Social Security Administration (SSA).

ACTION: Notice.

SUMMARY: The Commissioner of Social Security gives notice that an agreement coordinating the United States (U.S.) and Japanese social security programs entered into force on October 1, 2005. The agreement with Japan, which was signed on February 19, 2004, is similar to U.S. social security agreements already in force with 20 other countries—Australia, Austria, Belgium, Canada, Chile, Finland, France, Germany, Greece, Ireland, Italy, Korea (South), Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. Agreements of this type are authorized by section 233 of the Social Security Act (42 U.S.C. 433).

Like the other agreements, the U.S.-Japanese agreement eliminates dual social security coverage—the situation that exists when a worker from one country works in the other country and is covered under the social security systems of both countries for the same work. When dual coverage occurs, the worker or the worker's employer or both may be required to pay social security contributions to the two countries simultaneously. Under the U.S.-Japanese agreement, a worker who is sent by an employer in one country to work in the other country for 5 years or less remains covered only by the sending country. The agreement includes additional rules that eliminate dual U.S. and Japanese coverage in other work situations.

The agreement also helps eliminate situations where workers suffer a loss of benefit rights because they have divided their careers between the two countries. Under the agreement, workers may qualify for partial U.S. benefits or partial Japanese benefits based on combined (totalized) work credits from both countries.

Individuals who wish to obtain copies of the agreement or want more information about its provisions may write to the Social Security Administration, Office of International Programs, Post Office Box 17741, Baltimore, MD 21235–7741 or visit the Social Security Web site at *http://www.socialsecurity.gov/international*.

Dated: January 13, 2006.

Jo Anne B. Barnhart,

Commissioner of Social Security.

[FR Doc. E6–758 Filed 1–23–06; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 5280]

Title: Statement of Policy on J–1 Flight Training Programs

AGENCY: Department of State.

ACTION: Statement of policy.

DATES: *Effective Date:* This policy is effective January 24, 2006.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin, Director, Office of Exchange Coordination and Designation, U.S. Department of State, SA–44, 301 4th St., SW., Room 734, Washington, DC 20547. E-mail: *jexchanges@state.gov;* FAX: 202–203–5087.

SUMMARY: The Department hereby announces its policy regarding flight training programs, which are governed by the Department's Exchange Visitor Program regulations appearing in 22 CFR part 62.

Since 1949 the Department has designated private sector and governmental entities to conduct training programs for eligible foreign nationals. For the past twenty years, flight training activities have been authorized and currently, eight organizations facilitate the entry into the United States of some 350 foreign nationals yearly for the purpose of flight training. Flight training programs utilizing the J visa are regulated by the Department under the authority of the Mutual Educational and Cultural Exchange Act of 1961, as amended (Fulbright-Hays Act), 22 U.S.C. 2451 et seq.; the Immigration and Naturalization Act, 8 U.S.C. 1101(a)(15)(J); the Foreign Affairs Reform and Restructuring Act of 1998, Public Law 105–277; as well as other statutory enactments, Reorganization Plans and Executive Orders. Regulations dealing specifically with flight training programs appear at 22 CFR 62.22(n). Certain flight training programs also utilize the M visa, which is regulated and administered by the Department of Homeland Security's U.S. Citizenship and Immigration Services (USCIS). Regulations governing the M visa appear at 8 CFR 214.2(m).

The USA Patriot Act of 2001 (''The Uniting and Strengthening Act By Providing Appropriate Tools Required to Intercept and Obstruct Terrorism''), Public Law 107–56, mandated that the Department of State, the Department of Homeland Security, the Department of Education, and the Attorney General, all take cognizance of and undertake certain actions regarding flight training programs. The Department of State has determined that it does not have the expertise and resources to fully monitor flight training programs and insure their compliance with the national security concerns expressed in the Patriot Act. Consequently, as a matter of policy, the Department of State will henceforth not designate any new J visa flight training programs, nor will it permit currently-designated flight training programs to expand their programs, pending a determination as to which Federal agency ultimately will be tasked with the administering and monitoring of such programs. Redesignation of programs will continue as required by existing regulations.

Dated: January 18, 2006.

Stanley S. Colvin,

Director, Office of Exchange Coordination, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. E6–821 Filed 1–23–06; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 5262]

Arms Control and Nonproliferation Advisory Board (ACNAB) Meeting Notice; Closed Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app 2 section 10(a)(2), the Department of State announces a meeting of the Arms Control and Nonproliferation Advisory Board (ACNAB) to take place on January 30, 2006, at the Department of State, Washington, DC.

Pursuant to section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. app 2 section 10(d) and 5 U.S.C. 552b(c)(1), it has been determined that this Board meeting will be closed to the public in the interest of national defense and foreign policy because the Board will be reviewing and discussing matters classified in accordance with Executive Order 12958. The purpose of the ACNAB is to provide the Department with a continuing source of independent advice on all aspects of arms control, disarmament, international security, and public diplomacy. The Board will be briefed on current U.S. policy and issues regarding Weapons of Mass Destruction and Counter-Terrorism, as well as issues related to the Proliferation Security

Initiative (PSI). The Board will also review specific classified arms control and nonproliferation issues as potential first topics for the Board's consideration. In addition, the agenda will include administrative matters related to the Board's first meeting.

For Further Information Contact: Matthew Zartman, Deputy Executive Director of the Arms Control and Nonproliferation Advisory Board, Department of State, Washington, DC 20520, phone: (202) 647–0440.

Dated: January 9, 2006.

George W. Look,

Executive Director of the Secretary's Arms Control and Nonproliferation Advisory Board, Department of State.

[FR Doc. E6–822 Filed 1–23–06; 8:45 am]

BILLING CODE 4710–27–P

DEPARTMENT OF STATE

[Public Notice 5281]

Title: Statement of Policy on J–1 Agriculture Training Programs

AGENCY: Department of State.

ACTION: Statement of policy.

DATES: *Effective Date:* This policy is effective January 24, 2006.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin, Director, Office of Exchange Coordination and Designation, U.S. Department of State, SA–44, 301 4th St., SW., Room 734, Washington, DC 20547. E-mail: *jexchanges@state.gov;* FAX: 202–203–5087.

SUMMARY: The Department hereby announces its policy regarding agriculture training programs, which are governed by the Department's Exchange Visitor Program regulations appearing in 22 CFR part 62.

Since 1949 the Department has permitted designated sponsors to conduct programs designed to train individuals in many industrial, professional, agricultural, and other occupational skills. Training programs utilizing the J visa are regulated by the Department under the authority of the Mutual Educational and Cultural Exchange Act of 1961, as amended (Fulbright-Hays Act), 22 U.S.C. 2451 et seq.; the Immigration and Naturalization Act, 8 U.S.C. 1101(a)(15)(J); the Foreign Affairs Reform and Restructuring Act of 1998, Public Law 105–277; as well as other statutory enactments, Reorganization Plans and Executive Orders. Regulations dealing with training programs appear at 22 CFR 62.22.

In 2005, the Government Accountability Office (GAO) examined the Department's management of the J visa Summer Work Travel and Trainee programs to ensure that only authorized activities are carried out under the programs and to identify potential risks of the programs and the data available to the Department to assess those risks. (''Stronger Action Needed to Improve Oversight and Assess Risks of the Summer Work Travel and Trainee Categories of the Exchange Visitor Program,'' GAO–06–106, October 2005.)

Among other things, the GAO Report found that there was a potential that the trainee programs could be misused as employment programs and that trainees could be exploited by employers or other third parties. Agricultural training programs were found to be particularly problematic because of the potential for fraud. Abuses of the training regulations were not hidden; there were cases where there was not even an attempt to represent jobs as training, and which certain employers referred to their program participants as employees, rather than trainees. In one case cited, four trainees were placed with dairy farms that had an agreement with the program sponsor. Only one of the trainees had a firm grasp of English, and only one of the four farms participating in the program had a structured training plan. There were questions as to whether such programs were merely utilizing trainees for cheap labor and whether the trainees were simply receiving enough training to perform their work. (GAO Report, pp. 17, 21).

The Department has taken steps to address these concerns. Among other things, the Department has consulted with the Department of Labor and the Department of Agriculture in order to develop ways to better monitor agricultural training programs and to determine whether such agriculture training programs are subject to, and if so, whether they are in compliance with, existing statutes such as the Fair Labor Standards Act, as amended, 29 U.S.C. 201, et seq., and the Migrant and Seasonal Agricultural Workers Protection Act, Public Law 97–470, 29 U.S.C. 1801 et seq.

Pending the Department's resolution of these outstanding issues, the Department of State will not designate any new J visa agricultural training programs, nor will it permit currently-designated training programs offering agricultural training to expand the agricultural training component of their programs. Redesignation of programs will continue as required by existing regulations.

Dated: January 18, 2006.

Stanley S. Colvin,

Director, Office of Exchange Coordination, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. E6–820 Filed 1–23–06; 8:45 am]

BILLING CODE 4710–05–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Generalized System of Preferences (GSP): Notice of Closure of Case 017–CP–05, Protection of Intellectual Property in Pakistan, in the 2005 Annual Country Practice Review

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: This notice announces closure of the review for case 017–CP–05, Protection of Intellectual Property in Pakistan.

FOR FURTHER INFORMATION, CONTACT: Marideth Sandler, Executive Director of the GSP Program, Office of the United States Trade Representative (USTR), Room F–220, 1724 F Street, NW., Washington, DC 20508. The telephone number is (202) 395–6971 and the facsimile number is (202) 395–9481.

SUPPLEMENTARY INFORMATION: The GSP program provides for the duty-free importation of designated articles when imported from beneficiary developing countries. The GSP program is authorized by Title V of the Trade Act of 1974 (19 U.S.C. 2461, et seq.), as amended (the ''Trade Act''), and is implemented in accordance with Executive Order 11888 of November 24, 1975, as modified by subsequent Executive Orders and Presidential Proclamations.

In the 2005 Annual Review, the GSP Subcommittee of the Trade Policy Staff Committee (TPSC) is reviewing petitions concerning the country practices of certain beneficiary developing countries of the GSP program. As a result of that review, the TPSC has decided to close the review for case 017–CP–05 regarding protection of intellectual property rights in Pakistan. The Petitioner was the International Intellectual Property Alliance (IIPA). The results of other ongoing country practice reviews in the 2005 Annual Review will be announced in the **Federal Register** at a later date.

Marideth J. Sandler,

Executive Director, GSP Program.

[FR Doc. E6–809 Filed 1–23–06; 8:45 am]

BILLING CODE 3190–W6–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activity Under OMB Review, Request for Comments; Approval of a New Information Collection Activity, International Survey of Human Factors in Maintenance Organizations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: Organizations that are approved to conduct aircraft maintenance are certified and regulated under CFR 14, Title 49, FAR part 145, or international equivalent (Henceforth referred to as part 145). The information collected will be used to assess what companies have done, are doing or are planning to do regarding the human factors elements of part 145. A partial list of subjects includes training, error management, fatigue management, and additional human factors metrics. Additionally, respondents will be asked to describe their organization's support of their human factors program. This will involve collecting data from companies world-wide. The FAA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval of this new information collection. A notice for public comment was published in the **Federal Register** on 7/6/2005, vol. 70, #128, page 39000.

DATES: Please submit comments by February 23, 2006.

FOR FURTHER INFORMATION CONTACT: Judy Street on (202) 267–9895.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: International Survey of Human Factors in Maintenance Organizations.

*Type of Request:*Approval of a new collection.

OMB Control Number: 2120–xxxx.

Form(s): Human Factors Survey Form.

Affected Public: A total of 1,080 respondents.

Frequency: Conducted on an as-needed basis.

Estimated Average Burden Per Response: Approximately 30 minutes.

Estimated Annual Burden Hours: An estimated 540 hours annually.

Abstract: Part 145 organizations will receive an invitation via e-mail to complete a web-based survey. The information collected will be used to assess what companies have done, are doing or are planning to do regarding the human factors elements of part 145. A partial list of subjects includes training, error management, fatigue management, and additional human factors metrics. Additionally, respondents will be asked to describe their organization's support of their human factors program. This will involve collecting data from companies world-wide.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention FAA Desk Officer.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on January 13, 2006.

Judith D. Street,

FAA Information Collection Clearance Officer, Information Systems and Technology Services Staff, ABA–20.

[FR Doc. 06–596 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Extension of the Public Comment Period for the Draft Supplemental Environmental Assessment for the Proposed Modification to the Four Corner-Post Plan at Las Vegas McCarran International Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Extension of public comment period.

SUMMARY: This notice advises the public that the comment period for the Draft Supplemental Environmental Assessment (DSEA) for the proposed modification to the Four Corner-Post Plan at Las Vegas McCarran International Airport, Las Vegas, Nevada is extended.

DATES: The comment period of the DSEA, originally ending on December 30, 2005, and then extended to January 13, 2006, is now extended to March 14, 2006.

SUPPLEMENTARY INFORMATION: On November 22,2005, the Federal Aviation Administration (FAA) issued a notice of the availability of the DSEA for the Las Vegas McCarran International Airport. The notice published on December 5, 2005, FR Vol. 70, page 72497, also announced the schedule for public workshops regarding the DSEA, and advised that the public comment period would close Friday, December 30, 2005. The public workshops were held on November 12 and 13, 2005. A Notice of Extension of the Public Comment Period, published on December 16, 2006, FR Vol. 70, page 74864, extending the public comment period to January 13, 2006. The public comment period is further extended to March 14, 2006.

All written comments are to be submitted to Ms. Sara Hassert, Landrum & Brown, Inc., 8755 W. Higgins Rd., Ste. 850, Chicago, IL 60631, fax: 773–628–2901, E-mail: *shassert@landrum-brown.com* and the comments must be postmarked and e-mail/fax must be sent by no later than midnight, Tuesday, March 14, 2006.

FOR FURTHER INFORMATION CONTACT: Ms. Kathryn Higgins, Environmental Specialist, Western Terminal Service Area Office, FAA Western Terminal Operations, 15000 Aviation Blvd., Lawndale, CA 90261, Ph. 310–725–6597, E-mail: *kathryn.higgins@faa.gov.*

Issued in Lawndale, California on January 12, 2006.

Stephen Lloyd,

Manager, Operations Support, Western Terminal Service Area.

[FR Doc. 06–590 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Associate Administrator for Commercial Space Transportation; Notice of Intent To Prepare an Environmental Impact Statement (EIS) and Conduct Public Scoping Meetings

AGENCY: The Federal Aviation Administration (FAA), Associate Administrator for Commercial Space Transportation (AST) is the lead Federal agency. The Bureau of Land Management (BLM) is a cooperating agency. The FAA will ask the U.S. Department of the Army to participate as a cooperating agency.

ACTION: Notice of Intent.

SUMMARY: This Notice provides information to Federal, State, and local

agencies, affected Native American tribes, and other interested persons regarding the FAA's intent to prepare an environmental impact statement (EIS) for the New Mexico Economic Development Department's (NMEDD's) proposal to develop and operate a commercial launch site near Upham, New Mexico. The FAA will prepare the EIS in accordance with the National Environmental Policy Act (NEPA) of 1969 (42 United States Code (U.S.C.) 4321 *et seq.*), the Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA (40 Code of Federal Regulations (CFR) parts 1500–1508), and FAA Order 1050.1E, Environmental Impacts: Policies and Procedures, as part of its licensing process for the proposed launch site. The BLM will participate in this NEPA process as a cooperating agency; the FAA will ask the U.S. Army White Sands Missile Range to participate as a cooperating agency.

Under the proposed action, the FAA would issue a launch site operator license to the NMEDD to operate a launch facility at the proposed site, termed the Southwest Regional Spaceport. The launch site operator license would authorize the NMEDD to operate a launch facility to support launches of horizontally and vertically launched, suborbital rockets.[1] The vehicles proposed to be launched from the Southwest Regional Spaceport may carry space flight participants,[2] scientific experiments or other payloads.[3] The issuance of a launch site operator license does not permit the NMEDD to conduct launches, only to offer the facility and infrastructure to launch operators. All individual launch operators would be subject to separate FAA licensing or permitting.

A license to operate a launch site authorizes a licensee to offer its launch site to a launch operator for each launch point for the type and weight class of launch vehicle identified in the license application and upon which the licensing determination is based. Issuance of a license to operate a launch site does not relieve a licensee of its obligation to comply with any other laws or regulations; nor does it confer any proprietary, property, or exclusive right in the use of airspace or outer space. (14 CFR 420.41) A launch site operator license remains in effect for five years from the date of issuance unless surrendered, suspended, or revoked before the expiration of the term and is renewable upon application by the licensee. (14 CFR 420.43)

SUPPLEMENTARY INFORMATION:

Background

The FAA is preparing an EIS to analyze the environmental impacts of the NMEDD's proposed operation of a launch facility near Upham, New Mexico. The proposed site is located approximately 45 miles north of Las Cruces, New Mexico. The EIS will consider the environmental impacts of the construction of facilities, ground activities (*e.g.*, component testing, transportation and storage of propellants and explosives, etc.), pre-flight vehicle and payload preparation activities, launch, and landing/recovery operations.

The successful completion of the environmental review process does not guarantee that the FAA would issue a launch site operator license to the NMEDD. The project also must meet all FAA safety, risk, and indemnification requirements. A license to operate a launch site does not guarantee that a launch license or experimental permit would be granted for any particular launch proposed for the site.

Proposed Action

The proposed action is for the FAA to issue a launch site operator license to the NMEDD that would allow the NMEDD to operate the Southwest Regional Spaceport for both horizontal and vertical suborbital launches. Nominally, the rockets would return and land within the Southwest Regional Spaceport or adjacent areas. Contingency landings may occur on lands administered by BLM.

As part of the proposed action, the NMEDD proposes to construct a vertical launch area, airfield, spectator area, landing and recovery area, and access road. The vertical launch area would include: Storage areas for explosives and propellants, three launch pads, two vehicle assembly areas, launch control building, and office areas. The airfield would include prevailing and cross wind runways, and a horizontal launch hangar. The spectator area would include parking and viewing areas. These facilities would be constructed on State property. Development of access and supporting utility infrastructure for the Southwest Regional Spaceport may occur on lands administered by the BLM. The impacts of all construction activities will be analyzed in this EIS.

In order to address the range of launch vehicles that could be launched from the proposed facility, the EIS will consider three types of horizontally launched concept vehicles and three types of vertically launched concept vehicles. The horizontal concept vehicles include:

- Concept H1 vehicles—These vehicles use jet-powered take off with subsequent rocket engine ignition and powered horizontal landing.
- Concept H2 vehicles—These vehicles use rocket-powered take off and flight and unpowered horizontal landing.
- Concept H3 vehicles—These vehicles are carried aloft via assist aircraft with subsequent rocket engine ignition and unpowered horizontal landing.

The vertical concept vehicles include:

- Concept V1 vehicles—These vehicles consist of a single-stage rocket in which the rocket stage and payload or crew/passenger modules return separately to Earth by parachute.
- Concept V2 vehicles—These vehicles consist of a single-stage rocket in which the rocket stage returns to Earth by parachute and the crew/passenger module returns with a powered or unpowered horizontal landing.
- Concept V3 vehicles—These vehicles consist of a single-stage rocket with rocket-powered vertical landing.

Alternatives

Alternatives under consideration include issuance of a launch site operator license to the NMEDD for the operation of a launch site to support

- Horizontal launch concept vehicles only,
- Vertical launch concept vehicles only, or
- A subset of the concept vehicles.

Based on comments received during the scoping period, the FAA may propose additional alternatives. The EIS will also analyze the no action alternative.

Scoping Meetings

Two public scoping meetings will be held to solicit input from the public on potential issues that may need to be evaluated in the EIS. The first scoping meeting will be held on February 15 at 6:30 p.m., at the Truth or Consequences City Council Chambers, 405 West 3rd St. in Truth or Consequences, New Mexico. The second scoping meeting

[1] A suborbital rocket is a vehicle, rocket-propelled in whole or in part, intended for flight on a suborbital trajectory, and the thrust of which is greater than its lift for the majority of the rocket-powered portion of its ascent. (49 U.S.C 70102(19)) Suborbital trajectory is the intentional flight path of a launch vehicle, reentry vehicle, or any portion thereof whose vacuum instantaneous impact point (IIP) does not leave the surface of the Earth.

[2] 'Space flight participant' means an individual who is not crew, carried within a launch vehicle or reentry vehicle.

[3] Payload is the item that an aircraft or rocket carries over and above what is necessary for the operation of the vehicle in flight.

will be held on February 16, at 6:30 p.m., at the Physical Sciences Laboratory Auditorium, New Mexico State University in Las Cruces, New Mexico.

DATES: The FAA invites interested agencies, organizations, Native American tribes, and members of the public to submit comments or suggestions to assist in identifying significant environmental issues and in determining the appropriate scope of the EIS. The public scoping period starts with the publication of this notice in the **Federal Register**. To ensure sufficient time to consider issues identified during the public scoping period, comments should be submitted to Ms. Stacey M. Zee by one of the methods listed below no later than March 3, 2006.

ADDRESSES: Comments, statements, or questions concerning scoping issues or the EIS process should be mailed to Ms. Stacey M. Zee, FAA Environmental Specialist, Southwest Regional Spaceport EIS c/o ICF Consulting, 9300 Lee Highway, Fairfax, VA 22031. Comments can also be sent by e-mail to *SRSEIS@icfconsulting.com* or by fax to (703) 934–3951.

Dated: January 13, 2006.

Herbert Bachner,

Manager, Space Systems Development Division.

[FR Doc. E6–757 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2006–01]

Petitions for Exemption; Summary of Petitions Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before February 13, 2006.

ADDRESSES: You may submit comments [identified by DOT DMS Docket Number FAA–200X–XXXXX] by any of the following methods:

- Web site: *http://dms.dot.gov.* Follow the instructions for submitting comments on the DOT electronic docket site.
- Fax: 1–202–493–2251.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tim Adams (202) 267–8033, Sandy Buchanan-Sumter (202) 267–7271, or John Linsenmeyer (202) 267–5174, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC, on January 11, 2006.

Anthony F. Fazio,

Director, Office of Rulemaking.

Petitions for Exemption

Docket No.: FAA–2005–23189.

Petitioner: Brooks Air Transport d.b.a. Brooks Fuel, Inc.

Section of 14 CFR Affected: 14 CFR 125.224.

Description of Relief Sought: To allow Brooks Air Transport d.b.a. Brooks Fuel, Inc., to operate its Douglas C54G–DC without having a collision avoidance system that meets TSO C–118 installed on that aircraft.

[FR Doc. E6–753 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Third Meeting: RTCA Special Committee 206: Aeronautical Information Services Data Link

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of RTCA Special Committee 206 meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of RTCA Special Committee 206: Aeronautical Information Services Data Link.

DATES: The meeting will be held January 30–February 3, 2006, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at CASTOR Conference Room (Plenary) EUROCONTROL Headquarters, Rue de la Fusée, 96 1130 Brussells, Belgium.

FOR FURTHER INFORMATION CONTACT: RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington, DC, 20036–5133; telephone (202) 833–9339; fax (202) 833–9434; Web site *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 206 meeting. The agenda will include:

Monday, January 30:

- Opening Session (Chairman's Address, Welcome, Introductory and Administrative Remarks, Review Agenda, Approve minutes of the 2nd meeting,)
- Formal announcement of EUROCAE participation
- Working arrangements
- Nomination of chairman and secretary
- Status of Terms of Reference Overview and Discussions—Committee Chairmen
- Review of actions and discussion
- Presentations
- Communications Strategy
- Overview of the Cascade Program
- Future data Link applications
- Methodology and OSED development
- Breakout into Weather Data Link and AIS Data Link Subgroups

Tuesday, January 31–Thursday, February 2:

- Continue in Weather Data Link and AIS Data Link Subgroups

Friday, February 3:

- Continue in Weather Data Link and AIS Data Link Subgroups
- Chairman of Weather Subgroup Summary Presentation of Results and Meeting Outcome

• Chairwoman of AIS Subgroup Summary Presentation of Results and Meeting Outcome

• Closing Session (Other Business, Chairman Wrap Up and Conclusions, Data and Place of Next Meeting, Closing Remarks, Adjourn)

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on January 13, 2006.

Natalie Ogletree,

FAA General Engineer, RTCA Advisory Committee.

[FR Doc. 06–591 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Draft Advisory Circulars (ACs), Other Policy Documents, and Proposed Technical Standard Orders (TSOs)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Availability of draft advisory circulars (ACs), other policy documents, and proposed technical standard orders (TSOs).

SUMMARY: This notice announces that the Aircraft Certification Service of the FAA maintains the ''Aircraft Certification Draft Documents Open for Comment'' Web site on the Internet at *http://www.faa.gov/aircraft/draft_docs/* The Aircraft Certification Service will make available on this web site draft ACs, other policy documents, and proposed TSOs open for comment. The Aircraft Certification Service, FAA will no longer publish an individual **Federal Register** Notice for each draft AC, other policy documents, or proposed TSO that we make available for public comment. There is no requirement to publish these documents or notices in the **Federal Register.** Comments on the documents published on the website must be received on or before the due date specified on the web site for each document. The FAA will publish in the **Federal Register** a recurring generic Notice of Availability and Request for Comments announcement reminding the public to check the ''Aircraft Certification Draft Documents Open for Comments'' Web site on the Internet at *http://www.faa.gov/aircraft/draft_docs/*.

DATES: This notice becomes effective the date of publication in the **Federal Register.**

ADDRESSES: Send comments on draft ACs, other policy documents, and proposed TSOs electronically or in hard copy to the Federal Aviation Administration at the address specified on the web site to the attention of the individual and office identified as point of contact for the document.

FOR FURTHER INFORMATION CONTACT: Roberta Katson, production and Airworthiness Division, Aircraft Certification Service, AIR–200, Room 815, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. Telephone (202) 493–4633, Fax (202) 267–5580.

SUPPLEMENTARY INFORMATION: You are invited to comment on the documents provided on the website. Comments on draft ACs, other policy documents and proposed TSOs should identify the document by its number. The Director, Aircraft Certification Service, will consider all comments received on or before the closing date before issuing a final document. You can obtain a paper copy of the draft document by contacting the FAA individual or office responsible for the document. You will find the ''Aircraft Certification Draft Documents Open for Comment'' site at *http://www.faa.gov/aircraft/draft_docs/*. For Internet retrieval assistance, contact the AIR Internet Content Program manager at 202–267–8361.

Issued in Washington, DC on January 13, 2006.

Terry Allen,

Acting Manager, Production and Airworthiness Division, Aircraft Certification Service.

[FR Doc. 06–597 Filed 1–23–06; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF VETERANS AFFAIRS

National Research Advisory Council; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that the National Research Advisory Council will hold a meeting on Wednesday, February 1, 2006, in room 900 at the Greenhoot Cohen Building, 1722 I Street, NW., Washington, DC. The meeting will convene at 8:30 a.m. and conclude by 3 p.m. The meeting is open to the public.

The purpose of the Council is to provide external advice and review for VA's research mission.

The agenda will include a review of and discussion about the NRAC annual report for 2005, an overview of research, education, and clinical centers, and an update on deployment health and Gulf War research.

Any member of the public wishing to attend the meeting or wishing further information should contact Ms. Karen Scott, Designated Federal Officer, at (352) 392–8066. Oral comments from the public will not be accepted at the meeting. Written statements or comments should be transmitted electronically to *karen.scott@va.gov*.

Dated: January 13, 2006.

By direction of the Secretary.

E. Philip Riggin,

Committee Management Officer.

[FR Doc. 06–604 Filed 1–23–06; 8:45 am]

BILLING CODE 8320–01–M

Corrections

Federal Register

Vol. 71, No. 15

Tuesday, January 24, 2006

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 AGRICULTURE

Forest Service

RIN 0596–AC34

National Environmental Policy Act Documentation Needed for Oil and Gas Exploration and Development Activities (Categorical Exclusion)

Correction

In notice document 05–23983 beginning on page 73722 in the issue of Tuesday, December 13, 2005, make the following correction:

On page 73722, in the second column, under the **DATES** heading, ''February 13, 2005'' should read ''February 13, 2006''.

[FR Doc. C5–23983 Filed 1–23–06; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Intent to Prepare a Draft Supplemental Environmental Impact Statement/ Environmental Impact Report for the Yuba River Basin Project, Yuba County, CA

Correction

In notice document 06–483 beginning on page 3060 in the issue of Thursday, January 19, 2006, make the following correction:

On page 3060, in the second column, under the **FOR FURTHER INFORMATION CONTACT** heading, in the third line, ''*Robert.L.Roenigs*'' should read ''*Robert.L.Koenigs*''.

[FR Doc. C6–483 Filed 1–23–06; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Availability (NOA) for the Supplemental Final Environmental Impact Statement (SFEIS) for the Proposed Addition of Maneuver Training Land at Fort Irwin, CA

Correction

In notice document 06–475 appearing on page 3059 in the issue of Thursday, January 19, 2006, make the following correction:

In the second column, in the last paragraph, in the 2nd and 3rd lines, ''*http://fortirwindlandexpansion.com*'' should read ''*http://fortirwinlandexpansion.com.* ''

[FR Doc. C6–475 Filed 1–23–06; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Tuesday,
January 24, 2006

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 201, 314, and 601

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products and Draft Guidances and Two Guidances for Industry on the Content and Format of Labeling for Human Prescription Drug and Biological Products; Final Rule and Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 314, and 601

[Docket No. 2000N–1269] (formerly Docket No. 00N–1269)

RIN 0910–AA94

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing the content and format of labeling for human prescription drug products (including biological products that are regulated as drugs). The final rule revises current regulations to require that the labeling of new and recently approved products include highlights of prescribing information and a table of contents. The final rule also reorders certain sections, requires minor content changes, and sets minimum graphical requirements. These revisions will make it easier for health care practitioners to access, read, and use information in prescription drug labeling. The revisions will enhance the safe and effective use of prescription drug products and reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information. For both new and recently approved products and older products, the final rule requires that all FDA-approved patient labeling be reprinted with or accompany the labeling. The final rule also revises current regulations for prescription drug labeling of older products by clarifying certain requirements. These changes will make the labeling for older products more informative for health care practitioners.

DATES: This rule is effective June 30, 2006. See section III of this document for the implementation dates of this final rule.

FOR FURTHER INFORMATION CONTACT:

For information on drug product labeling: Janet Norden, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4202, Silver Spring, MD 20993–0002, 301–796–2270, *nordenj@CDER.FDA.GOV*, or Elizabeth Sadove, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041, *sadovee@CDER.FDA.GOV*.

For information on labeling of biological products that are regulated as prescription drugs: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20856, 301–827–6190, *stifano@CBER.FDA.GOV*, or Kathleen Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
II. Overview of the Final Rule Including Changes to the Proposed Rule
III. Implementation
IV. Overview of Agency Initiatives to Improve the Content and Format of Prescription Drug Labeling
V. Implications of This Final Rule for the Electronic Labeling Initiative
VI. Comments on the Proposed Rule
VII. Legal Authority
VIII. Paperwork Reduction Act of 1995
IX. Environmental Impact
X. Executive Order 13132: Federalism
XI. Analysis of Economic Impacts
XII. Executive Order 12988: Civil Justice Reform
XIII. References

I. Background

In the **Federal Register** of December 22, 2000 (65 FR 81082), FDA issued a proposed rule to revise its regulations governing the content and format of labeling for human prescription drug products, which appear in §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57).[1]

A. FDA-Approved Prescription Drug Labeling

A prescription drug product's FDA-approved labeling (also known as ''professional labeling,'' ''package insert,'' ''direction circular,'' or ''package circular'') is a compilation of information about the product, approved by FDA, based on the agency's thorough analysis of the new drug application (NDA) or biologics license application (BLA) submitted by the applicant. This labeling contains information necessary for safe and effective use. It is written for the health care practitioner audience, because prescription drugs require ''professional supervision of a practitioner licensed by law to administer such drug'' (section 503(b) of the act (21 U.S.C. 353(b))). FDA-approved labeling is defined in section 201(m) of the act (21 U.S.C. 321(m)) and is subject to all applicable provisions of section 502 of the act (21 U.S.C. 352). It satisfies the requirement of § 201.100(d) (21 CFR 201.100(d)) that ''[a]ny labeling, as defined in section 201(m) of the act * * * that furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for the use of the drug * * * contains * * * [a]dequate information for such use,'' as further described in that provision. FDA-approved labeling also accompanies ''promotional'' materials, as described in § 202.1(l)(2) (21 CFR 202.1(l)(2)). FDA-approved labeling also ''bears adequate information'' within the meaning of § 201.100(c)(1), which applies to ''labeling on or within the package from which a prescription drug is to be dispensed'', referred to in this document as ''trade labeling.'' In this document, FDA-approved labeling for prescription drugs is referred to as ''labeling'' or ''prescription drug labeling.''

B. Developing the Proposed Rule

In recent years, there has been an increase in the length, detail, and complexity of prescription drug labeling, making it harder for health care practitioners to find specific information and to discern the most critical information. Before issuing the proposal, the agency evaluated the usefulness of prescription drug labeling for its principal audience to determine whether, and how, its content and format could be improved. The agency used focus groups, a national physician survey, a public meeting, and written comments to develop multiple prototypes and to ascertain how prescription drug labeling is used by health care practitioners, what labeling information practitioners consider most important, and how practitioners believed labeling could be improved. The agency developed a prototype based on this accumulated information as the model for the proposed rule.

[1] Although §§ 201.56 and 201.57 do not specifically mention the term ''biologics'', under the Federal Food, Drug, and Cosmetic Act (the act), most biologics are drugs that require a prescription and thus are subject to these regulations. (See section VII of this document for legal authority.) For the purposes of this document, unless otherwise specified, all references to ''drugs'' or ''drug products'' include human prescription drug products and biological products that are also drugs.

C. The Proposed Rule

The agency's proposed changes were designed to enhance the ability of health care practitioners to access, read, and use prescription drug labeling.

1. Proposed Provisions for New and Recently Approved Drugs

FDA proposed the following changes for the labeling for prescription drugs that were approved on or after the effective date of the final rule, drugs that had been approved in the 5 years before the effective date of the final rule, and older approved drugs for which an efficacy supplement is submitted. FDA believed that applying the revised content and format requirements only to more recently approved products was appropriate because, among other reasons, health care practitioners are more likely to refer to the labeling of recently approved products (see comment 113).

- The addition of introductory prescribing information, entitled ''Highlights of Prescribing Information'' (Highlights).
- The addition of a table of contents.
- Reordering and reorganizing to make the labeling easier to use and read.
- Minimum graphical requirements for format.
- Certain revisions to the content requirements, such as modifying the definition of ''adverse reaction'' to make the ''Adverse Reactions'' section of labeling more meaningful and useful to health care practitioners.

2. Proposed Provisions for Older Approved Drugs

The agency proposed that older approved drug products would not be subject to these proposed changes. These older products would, instead, be subject to the labeling requirements at proposed § 201.80. The agency proposed to redesignate then-current § 201.57 as § 201.80 to describe labeling requirements for older drugs and add new § 201.57 to describe labeling requirements for new and recently approved drugs.

3. Proposed Provisions for All Drugs

FDA also proposed certain revisions to the requirements governing the content of labeling to help ensure that statements appearing in labeling related to effectiveness or dosage and administration are sufficiently supported. These provisions would have applied to all drugs.

- The labeling for all drugs would contain all FDA-approved patient labeling (i.e., approved printed patient information and Medication Guides) for the drug, not just the information required by regulation to be distributed to patients (see table 2).
- Minor revisions would be made to the requirements for labels affixed to prescription drug containers and packaging.

The proposal called for the submission of comments by March 22, 2001. At the request of the Pharmaceutical Research and Manufacturers of America, and to provide all interested persons additional time to comment, the comment period was reopened until June 22, 2001 (66 FR 17375, March 30, 2001). After careful consideration of the comments, FDA has revised the proposal and is issuing this final rule.

The following sections of this document provide:

- An overview of the final rule including changes to the proposed rule (section II of this document),
- A discussion of the implementation requirements for the final rule (section III of this document),
- An overview of the agency's prescription drug labeling initiatives (section IV of this document),
- The implications of this rule for the electronic labeling initiative (section V of this document),
- A discussion of the comments received on the proposal and the agency's responses to the comments (section VI of this document),
- A statement of legal authority (section VII of this document),
- A description of the information collection provisions of the rule (section VIII of this document),
- An statement on the environmental impact of the rule (section IX of this document),
- A statement on federalism (section X of this document),
- An analysis of the economic impacts of the rule (section XI of this document),
- A statement on the impact of the rule on the civil justice system (section XII of this document), and
- A list of references (section XIII of this document).

II. Overview of the Final Rule Including Changes to the Proposed Rule

This final rule amends part 201 (21 CFR part 201) of FDA regulations by revising the requirements for the content and format of labeling for prescription drug products (see tables 1 and 2 of this document). Table 1 lists the sections required for prescription drug labeling before the effective date of this final rule (and which will remain in effect for older products), and, for new and recently approved products, the sections FDA proposed in 2000 and those required by this final rule.

BILLING CODE 4160–01–S

Table 1.--Prescription Drug Labeling Sections

Sections Required for All Products Before the Effective Date of the Final Rule and for Older Products On and After the Effective Date of the Final Rule	Sections That Were Proposed for New and Recently Approved Products	Sections Required for New and Recently Approved Products On or After the Effective Date of the Final Rule
Description Clinical Pharmacology Indications and Usage Contraindications Warnings Precautions Adverse Reactions Drug Abuse and Dependence Overdosage Dosage and Administration How Supplied Optional: Animal Pharmacology and/or Animal Toxicology Clinical Studies References	Highlights of Prescribing Information Product Names, Other Required and Optional Information Boxed Warning Recent Labeling Changes Indications and Usage Dosage and Administration How Supplied Contraindications Warnings/Precautions Drug Interactions Use in Specific Populations Comprehensive Prescribing Information: Index Comprehensive Prescribing Information ! Boxed Warning 1 Indications and Usage 2 Dosage and Administration 3 How Supplied/Storage and Handling 4 Contraindications 5 Warnings/Precautions 6 Drug Interactions 7 Use in Specific Populations 8 Adverse Reactions 9 Drug Abuse and Dependence 10 Overdosage 11 Description 12 Clinical Pharmacology 13 Nonclinical Toxicology 14 Clinical Studies R References P Patient Counseling Information	Highlights of Prescribing Information Product Names, Other Required Information Boxed Warning Recent Major Changes Indications and Usage Dosage and Administration Dosage Forms and Strengths Contraindications Warnings and Precautions Adverse Reactions Drug Interactions Use in Specific Populations Full Prescribing Information: Contents Full Prescribing Information Boxed Warning 1 Indications and Usage 2 Dosage and Administration 3 Dosage Forms and Strengths 4 Contraindications 5 Warnings and Precautions 6 Adverse Reactions 7 Drug Interactions 8 Use in Specific Populations 9 Drug Abuse and Dependence 10 Overdosage 11 Description 12 Clinical Pharmacology 13 Nonclinical Toxicology 14 Clinical Studies 15 References 16 How Supplied/Storage and Handling 17 Patient Counseling Information

The final rule requires that any FDA-approved patient labeling either: (1) Accompany the prescription drug labeling or (2) be reprinted at the end of such labeling (§§ 201.57(c)(18) and 201.80(f)(2)). Table 2 lists the requirement in effect before the effective date of this final rule, the 2000 proposed requirement, and the final requirement (see comment 92 for discussion of FDA-approved patient labeling). For the purposes of this document, the term "FDA-approved patient labeling" will be used to refer to any approved printed patient information or Medication Guide, unless a comment is addressing one or the other specifically.

TABLE 2.—FDA-APPROVED PATIENT LABELING WITH PRESCRIPTION DRUG LABELING

Requirement for All Products Before the Effective Date of the Final Rule	Proposed Requirement for All Products	Final Requirement for All Products
To be reprinted at the end of labeling: • Full text of FDA-approved patient labeling that is required to be distributed to patients	To be reprinted at the end of labeling: • Full text of any FDA-approved patient labeling	To be reprinted at the end of labeling or to accompany the labeling: • Full text of any FDA-approved patient labeling

In this rulemaking, the agency finalizes many of the provisions in the December 2000 proposal. In addition, the final rule reflects revisions the agency made in response to comments on the December 2000 proposal and revisions made by the agency on its own initiative. FDA also has made editorial changes to clarify provisions, correct cross-references, and support the agency's plain language initiative. Table 3 lists the substantive changes made to the general provisions and Highlights and table 4 lists the substantive changes made to the Full Prescribing Information (FPI).

A. Content and Format of Labeling for New and More Recently Approved Prescription Drug Products

The final rule, like the proposed rule, requires that the labeling for new and more recently approved drug products comply with revised content and format requirements (§ 201.56(d)) (see table 1). Like the proposed rule, the final rule provides that new and more recently approved products include drug products with an NDA, BLA, or efficacy supplement that: (1) Was approved between June 30, 2001, and June 30, 2006; (2) is pending on June 30, 2006; or (3) is submitted anytime on or after June 30, 2006 (§ 201.56(b)(1)).

On its own initiative, the agency added a provision on pediatric risk information to the general labeling requirements of the final rule. Section 11 of the Best Pharmaceuticals for Children Act (Public Law 107–109) (BPCA), which was signed into law on January 4, 2001, addresses labeling requirements for generic versions of drugs with pediatric patent protection or exclusivity. The agency added a provision in § 201.56(d)(5) of the final rule to make clear that any risk information from the ''Contraindications,'' ''Warnings and Precautions,'' or ''Use in Specific Populations'' section is ''pediatric contraindications, warnings, or precautions'' within the meaning of section 11 of the BPCA (21 U.S.C. 355A(l)(2)). By adding § 201.56(d)(5), the agency intends to avoid any possible confusion as to what information the agency may require in generic labeling that otherwise omits a pediatric indication or other aspect of labeling pertaining to pediatric use protected by patent or exclusivity.

In addition, the agency declined to adopt the use of symbols that were proposed to emphasize or identify information in prescription drug labeling. Based on comments, FDA declined to use the inverted black triangle (see comment 15) and the exclamation point (!) to emphasize the boxed warning (see comment 43). On its own initiative, for the same reasons that FDA rejected use of the two symbols commented upon, FDA declined to use the following three proposed symbols:

• The Rx symbol (proposed § 201.57(a)(3)) in Highlights. The agency proposed the symbol to identify a product that is available only by prescription under section 503(b) of the act. The agency decided that the Rx symbol in Highlights is unnecessary because the new prescription drug labeling format is so distinct from the over-the-counter (OTC) drug labeling format that it will be clear to prescribers that labeling in the new format is for a prescription drug product.

• The ''R'' symbol in the FPI (proposed § 201.56(d)(2)), which would have identified the ''References'' section.

• The ''P'' symbol in the FPI (proposed § 201.57(c)(18)), which would have identified the ''Patient Counseling Information'' section.

1. Highlights of Prescribing Information

Like the proposed rule, the final rule requires that the labeling for new and more recently approved products include introductory information entitled ''Highlights of Prescribing Information'' (Highlights) (§§ 201.56(d)(1) and 201.57(a)) (see table 1).

The final rule requires the same headings for Highlights as proposed, except that, in response to comments, FDA moved ''Most Common Adverse Reactions'' from ''Warnings and Precautions'' (proposed § 201.57(a)(10)) to a new heading entitled ''Adverse Reactions'' (§§ 201.56(d)(1) and 201.57(a)(11)) (see table 1 and comment 28). Like the proposed rule, the final rule requires that Highlights, except for the boxed warning, be limited in length to one-half of the page (§ 201.57(d)(8)) (see comment 104).

The agency is also revising its regulations on supplements and other changes to an approved application in §§ 314.70 and 601.12 (21 CFR 314.70 and 601.12) to require applicants to obtain prior approval of any labeling changes to Highlights, except for identified minor changes (see comment 5).

TABLE 3.—SUBSTANTIVE CHANGES FROM THE PROPOSED RULE TO THE FINAL RULE: GENERAL PROVISIONS AND TO HIGHLIGHTS

21 CFR Section in Final Rule	Description of Change from Proposed Rule See comment or section of this document (identified in parentheses) for more detailed information regarding the change.
201.55, 201.57(c)(4)(v), 201.57(c)(12)(i)(D), and 201.100(b)	Container Labels • Withdrew proposed amendments regarding content of container labels and associated proposed amendments to the labeling (106 and 107)

TABLE 3.—SUBSTANTIVE CHANGES FROM THE PROPOSED RULE TO THE FINAL RULE: GENERAL PROVISIONS AND TO HIGHLIGHTS—Continued

21 CFR Section in Final Rule	Description of Change from Proposed Rule See comment or section of this document (identified in parentheses) for more detailed information regarding the change.
201.56(a)(2)	General Requirement • Revised to clarify that the labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading (114)
201.56(d)	Product Title • Deleted proposed § 201.56(d)(4), which permitted a ''Product Title'' section to be included at the beginning of the FPI (39)
201.56(d)(4)	Format of Contents • Revised to require that the Contents identify if sections have been omitted (37)
201.56(d)(5)	Pediatric Risk Information • Added, on its own initiative, a provision to make clear that pediatric risk information within the meaning of the BPCA may be located in the ''Use in Specific Populations'' section (II.A)
201.57 and 201.80	Unsubstantiated Claims • Removed the 1-year implementation requirement for provisions in §§ 201.57 and 201.80 that prohibit inclusion of unsubstantiated claims in labeling (114)
201.57	Promotional Labeling • Removed, on its own initiative, the reference to statements made in promotional labeling and advertising in proposed 201.57(a) (111)
201.57(a)(1)	Highlights Limitation Statement • Moved the Highlights limitation statement to the beginning of Highlights (35)
201.57(a)(3)	Inverted Black Triangle Symbol • Instead of an inverted black triangle symbol, labeling will state the ''Initial U.S. Approval'' date (15)
201.57(a)(4)	Boxed Warning • Revised to require that Highlights contain a concise summary of any boxed warning in the FPI (16)
201.57(a)(5)	Recent Labeling Changes • Changed the heading to ''Recent Major Changes'' and revised to identify only substantive changes to the ''Boxed Warning,'' ''Indications and Usage,'' ''Dosage and Administration,'' ''Contraindications,'' and ''Warnings and Precautions'' sections and the date of the change(s) (18–22)
201.57(a)(6)	Indications and Usage • Revised to require identification of the pharmacologic class of the drug if it is a member of an established pharmacologic class (6)
201.57(a)(8)	How Supplied • Changed the heading to ''Dosage Forms and Strengths'' (41)
201.57(a)(11)	Adverse Reactions • Moved ''Most Common Adverse Reactions'' from ''Warnings and Precautions'' to a new heading: ''Adverse Reactions'' (28) • Revised the criteria used for determining which adverse reactions to include in Highlights and that the criteria used be specified (28) • Revised to require that the adverse reactions reporting contact statement be included under the ''Adverse Reactions'' heading of Highlights; deleted proposed § 201.57(c)(6)(v) that would have required that this statement also be included in the FPI (28 and 30) • Revised the requirements associated with the adverse reactions reporting contact statement (31 and 32)
201.58	Waiver Provision • Revised to make clear applicants can request waivers from any requirement under §§ 201.56, 201.57, and 201.80 (104)

2. Full Prescribing Information: Contents

Like the proposed rule, the final rule requires that the labeling for new and recently approved products include, after Highlights, a list of headings and subheadings contained in the FPI preceded by the numerical identifier for the heading or subheading (§ 201.57(b)). FDA has revised, on its own initiative, the heading for this portion of the labeling to read ''Full Prescribing Information: Contents'' (Contents) instead of proposed ''Comprehensive Prescribing Information: Index.'' FDA made this change for editorial reasons to correctly reflect the function of the section. In response to comments, FDA added certain format requirements for the Contents (see table 3 and comments 37 and 101).

3. Full Prescribing Information

FDA has revised, on its own initiative, the heading for this portion of the labeling to read ''Full Prescribing Information'' instead of proposed ''Comprehensive Prescribing Information.'' FDA made this change to more accurately reflect that this portion of prescription drug labeling contains the information that FDA determined is necessary for the safe and effective use of the drug, but may not contain all known information about the drug (e.g., details of all clinical trials).

The final rule revises the requirements for the content and format of the FPI in former §§ 201.56(d) and 201.57 for new and recently approved products (see tables 1 and 2). The final rule establishes minimum requirements for key graphic elements, including bold type, bullet points, type size, spacing and use of vertical and horizontal lines. The final rule requires the same sections for the labeling of these products as proposed except the major, substantive changes listed in table 4, which the agency made in response to comments and, in a few cases as noted, on its own initiative. In addition, FDA made revisions, none of which changed substantive requirements, to the ''Dosage and Administration,'' ''Indications and Usage,'' ''Overdosage,'' ''Clinical Pharmacology,'' and ''Drug Interactions'' sections. FDA made these changes in response to comments that requested FDA to clarify these proposed requirements.

In addition, FDA has revised, on its own initiative, ''Contraindications'' to emphasize that the section must only describe situations in which the potential risks associated with drug use outweigh any possible benefit. FDA believes that including relative or hypothetical hazards diminishes the usefulness of the section. For clarity and emphasis, FDA is requiring that ''none'' be stated when no contraindications are known. Similarly, FDA deleted, on its own initiative, proposed § 201.57(c)(9)(iii) because it was redundant with requirements in ''Warnings and Precautions'' and ''Contraindications.''

TABLE 4.—SUBSTANTIVE CHANGES FROM THE PROPOSED RULE TO THE FINAL RULE: FULL PRESCRIBING INFORMATION

21 CFR Section in Final Rule	Description of Change From Proposed Rule See comment or section of this document (identified in parentheses) for more detailed information regarding the change.
201.57(c)(3)	Dosage and Administration • Revised to make clear that this section must include dosing recommendations based on clinical pharmacologic data, certain dosage modifications, and specified compliance information (51–54)
201.57(c)(4) and 201.57(c)(17)	How Supplied/Storage and Handling • Reorganized information in proposed ''How Supplied/Storage and Handling'' (§ 201.57(c)(4)) such that the information is now contained in two sections: § 201.57(c)(4) retitled ''Dosage Forms and Strengths'' and ''How Supplied/Storage and Handling'' at § 201.57(c)(17) (41)
201.57(c)(7)	Adverse Reactions • Moved the ''Adverse Reactions'' section (proposed § 201.57(c)(9)) to follow ''Warnings and Precautions'' (38) • Withdrew the proposed definition of adverse reaction and retained the definition at former § 201.57(g) (designated in this final rule at § 201.80(g)), with a minor modification (68) • Revised the requirements on how to classify and categorize adverse reactions and how to describe adverse reaction rates (71-75) • Revised to require a description of the overall adverse reaction profile based on entire safety database (70 and 77)
201.57(c)(9)	Use in Specific Populations • Withdrew the proposed warning statements at §§ 201.57(c)(8)(i)(A)(4) and (c)(8)(i)(A)(5) for pregnancy categories D and X and will continue to require the warning statements at former §§ 201.57(f)(6)(i)(d) and (f)(6)(i)(e) be used (66) • Withdrew the proposed revisions for the ''Nursing Mothers'' subsection at § 201.57(c)(8)(iii) and will continue to use the language at former § 201.57(f)(8) (66)
201.57(c)(13)(ii) and 201.80(b)(2)	In Vitro Data for Anti-infectives • Deferred action on proposed §§ 201.57(c)(13)(ii) and 201.80(b)(2) that would have only permitted in vitro data for anti-infective drugs not shown by adequate and well-controlled studies to be pertinent to clinical use be included in labeling if a waiver was granted (81)
201.57(c)(18) and 201.80(f)(2)	Patient Counseling Information • Revised to require that the full text of FDA-approved patient labeling either accompany labeling or be reprinted at the end of the labeling and clarified the type size requirements that apply (93 and 94)(see table 7)
201.57(d)(6)	Font size • Revised to require that font for trade labeling be a minimum of 6-point type instead of 8-point type (102)
201.57(c)(16) and 201.80(l)	References • Clarified requirements for including a reference (89)

B. Content and Format for Older Prescription Drug Products

Like the proposed rule, the final rule redesignates former § 201.57 as § 201.80. New § 201.80 provides content and format requirements for labeling of older prescription drug products (older products) that are not subject to the labeling requirements at new § 201.57 (see tables 1 and 2).

Section 201.80 is the same as former § 201.57 with the following exceptions that are the same as the changes for new and more recently approved products:

- Modifications that help ensure that statements currently appearing in labeling for older products relating to effectiveness or dosage and administration are sufficiently supported (§ 201.80(c)(2)(i), (c)(2)(ii), (j), and (m)(1)).
- Deletion of proposed § 201.80(b)(2) regarding in vitro data for anti-infectives (see table 4 and comment 81).
- Deletion of ''induced emesis'' as an example of treatment procedures in the ''Overdosage'' section of labeling.
- Revisions that allow manufacturers the option of either reprinting the FDA-approved patient labeling immediately following the last section of the prescription drug labeling or having it accompany such labeling (§ 201.80(f)(2))(see table 4 and comment 93).
- Addition of the font size provision to redesignated § 201.80(f)(2) (on the agency's own initiative with modifications made in response to comments) (see table 4 and comments 93 and 94).

C. Content of Prescription Drug Product Labels

FDA has reconsidered its proposal to revise the requirements for the content of prescription drug product labels (proposed §§ 201.55 and 201.100(b)). In response to comments, FDA has decided to withdraw these proposed revisions at this time (see comments 106 and 107). The agency had proposed to move certain information about inactive ingredients and storage conditions from the product label to the prescription drug labeling and to remove the requirement to include the statement ''See package insert for dosage information'' on the product label in cases when it is currently required to be used. These proposed requirements (proposed § 201.57(c)(4)(v) and (c)(12)(i)(D)) were also withdrawn.

The agency intends to conduct a comprehensive evaluation of information required to be contained on product labels. If necessary, FDA will propose changes to these requirements after that evaluation has been completed.

III. Implementation

The final rule is effective June 30, 2006. The final rule has the same implementation plan as proposed for the revised labeling content and format requirements at §§ 201.56(d) and 201.57 for new and more recently approved products (see table 5). Manufacturers of older products that voluntarily elect to revise the format and content of their labeling to be consistent with §§ 201.56(d) and 201.57 may submit a supplement with proposed labeling at any time (see table 5).

TABLE 5.—IMPLEMENTATION PLAN

Applications (NDAs, BLAs, and Efficacy Supplements) Required to Conform to New Labeling Requirements	Time by Which Conforming Labeling Must Be Submitted to the Agency for Approval
Applications submitted on or after June 30, 2006	Time of submission
Applications pending on June 30, 2006 and applications approved 0 to 1 year before June 30, 2006	June 30, 2009
Applications approved 1 to 2 years before June 30, 2006	June 30, 2010
Applications approved 2 to 3 years before June 30, 2006	June 30, 2011
Applications approved 3 to 4 years before June 30, 2006	June 30, 2012
Applications approved 4 to 5 years before June 30, 2006	June 30, 2013
Applications approved more than 5 years before June 30, 2006	Voluntarily at any time

As indicated in the proposed rule, the implementation plan for revised labeling for products approved or submitted for approval under an ANDA depends on the labeling of the listed drug referenced in the ANDA. In accordance with § 314.94(a)(8) (21 CFR 314.94(a)(8)), the labeling of a drug product submitted for approval under an ANDA must be the same as the labeling of the listed drug referenced in the ANDA, except for changes required because of differences approved under a suitability petition (§ 314.93 (21 CFR 314.93)) or because the drug product and the reference listed drug are produced or distributed by different manufacturers.

As the agency proposed (65 FR at 81099), the provisions requiring FDA-approved patient labeling to accompany labeling (§§ 201.57(c)(18) and 201.80(f)(2) of the final rule) will be implemented by June 30, 2007. The agency clarified this provision at §§ 201.57 and 201.56(e)(6).

IV. Overview of Agency Initiatives to Improve the Content and Format of Prescription Drug Labeling

The agency is engaged in a broad effort to improve the communication to health care practitioners of information necessary for the safe and effective use of prescription drugs. A major component of this effort is improvement of the content and format of prescription drug labeling to make the information in labeling easier for health care practitioners to access, read, and use.

Elsewhere in this issue of the **Federal Register**, the agency is announcing the availability of four guidance documents on content and format of labeling.[2] These guidances are intended to assist manufacturers and FDA reviewers in developing clear, concise, and

[2] The agency announces the availability of guidances in the **Federal Register**. Draft and final guidances for the Center for Drug Evaluation and Research (CDER)-related information are posted on the Internet at *http://www.fda.gov/cder/guidance/index.htm*. The Center for Biologics Evaluation and Research (CBER)-related information is posted at *http://www.fda.gov/cber/guidelines.htm* (21 U.S.C. 371(h), 21 CFR 10.115).

accessible prescription drug labeling. The four guidances are as follows:

1. A draft guidance entitled ''Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements'' (the new labeling format guidance). This guidance, which is intended to assist manufacturers in complying with the provisions of this final rule, includes, among other things, how to determine what information from the FPI should be included in Highlights.

2. A draft guidance entitled ''Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format'' (the ''Warnings and Precautions'' section guidance).

3. A guidance entitled ''Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format '' (the ''Adverse Reactions'' section guidance). The agency issued a draft of this guidance on June 21, 2000 (65 FR 38563).

4. A guidance entitled ''Clinical Studies Section of Labeling for Prescription Drug and Biological Products—Content and Format'' (the ''Clinical Studies'' section guidance). The agency issued a draft of this guidance on July 9, 2001 (66 FR 35797).

The agency is also developing two additional guidances on the content and format of specific sections of labeling—the ''Clinical Pharmacology'' and ''Dosage and Administration'' sections. In the future, the agency may develop guidance for additional sections of prescription drug labeling, if necessary.

FDA has undertaken additional rulemaking related to prescription drug labeling. The agency published a final rule in the **Federal Register** entitled ''Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use'' that became effective on February 4, 2004 (68 FR 6062, February 6, 2003). This rule requires that the labeling for all systemic antibacterial drug products (i.e., antibiotics and their synthetic counterparts) intended for human use include certain statements about using antibiotics in a way that will reduce the development of drug-resistant bacterial strains. The rule encourages health care practitioners: (1) To prescribe systemic antibacterial drugs only when clinically indicated and (2) to counsel their patients about the proper use of such drugs and the importance of taking them exactly as directed.

The agency is also engaged in an effort to revise the regulations concerning the content and format of the ''Pregnancy'' subsection of prescription drug labeling (see the notice of a 21 CFR part 15 hearing to discuss the pregnancy category requirements (62 FR 41061, July 31, 1997) and the notice of a public advisory committee meeting to discuss possible changes to pregnancy labeling (64 FR 23340, April 30, 1999)).

V. Implications of This Final Rule for the Electronic Labeling Initiative

Developing standards for the conversion of paper labeling to an electronic format is a high priority for the agency. On December 11, 2003, FDA published its final rule in the **Federal Register** entitled ''Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format'' (68 FR 69009). The final rule requires the content of prescription drug labeling, including text, tables, and figures, to be submitted to FDA in an electronic format that the agency can process, review, and archive.

The agency views this final rule on the content and format of labeling as an essential step towards the success of its electronic labeling initiative. The labeling format required by this rule for new and more recently approved products should facilitate transition to an electronic format. The agency believes that an electronic version of labeling in the new format, particularly Highlights and Contents, will significantly expand health care practitioners' ability to access information in prescription drug labeling, enable them to rapidly obtain answers to questions for a range of drug products, and ultimately facilitate the development of a comprehensive repository for drug labeling. For example, FDA envisions that an electronic version of the new format will eventually enable health care practitioners to quickly access labeling information for all drugs in a pharmacologic or therapeutic class with a single electronic query.

FDA realizes that this final rule will affect the agency's existing electronic labeling requirements and guidances and will work to ensure consistency with the electronic labeling initiative.[3] The agency believes the electronic labeling initiative, in conjunction with this new format for labeling described in this final rule, could dramatically improve the way practitioners obtain information about prescription drugs and, as a consequence, significantly improve patient care.

VI. Comments on the Proposed Rule

The agency received 97 comments on the December 22, 2000, proposal. Comments were received from prescription drug manufacturers and related companies; trade organizations representing prescription drug manufacturers and other interested parties; professional associations and organizations representing health care practitioners; health care and consumer advocacy organizations; individual physicians, pharmacists, and consumers; and others.

A. General Comments on the Proposed Rule

Most comments expressed broad agreement that prescription drug labeling could be more effective in communicating drug information to health care practitioners and overwhelming support for the agency's goal of improving the content and format of prescription drug labeling to make information easier for health care practitioners to access, read, and use.

Many comments expressed approval of all the major features of the proposal, indicating that the proposed changes represent an important improvement in the organization, clarity, and overall usefulness of prescription drug labeling. For example, there was near universal support for the proposal to place at the front of labeling those sections that practitioners refer to most frequently and consider most important, although some comments recommended sequences slightly different from those proposed by FDA (see section VI.G of this document). There was also broad support for restructuring the old ''Precautions'' section into new sections devoted to use in specific populations, drug interactions, and patient counseling information and for combining the remainder of the ''Precautions'' section with the ''Warnings'' section.

Comments from manufacturers, while strongly supportive of the agency's efforts to improve the content and format of labeling, generally expressed concerns about some of the major elements of the proposal. In particular, as discussed in greater detail in sections VI.C and VI.D of this document, many manufacturers were concerned about the inclusion of Highlights. Manufacturers also expressed concern about the proposed requirements to re-evaluate, within 1 year of the effective

[3] See *http://www.fda.gov/cder/guidance/index.htm* under ''Electronic Submissions'' and *http://www.fda.gov/cber/guidelines.htm* for the most recent guidances on submission of labeling in an electronic format for drug and biological products, respectively.

date of the final rule, all prescription drug labeling to identify and remove any claims for indications and dosing regimens that are not supported by substantial evidence and to remove in vitro data that are not supported by clinical data.

Specific issues raised by the comments and the agency's responses follow.

B. Comments on the Process for Development of the Proposed Rule

As discussed in detail in the preamble to the proposed rule, FDA relied on focus group testing of physicians, a national physician survey, and a public meeting held in 1995 to develop the labeling prototype that was used as the basis for the proposal (65 FR 81082 at 81083 through 81085).

(Comment 1) Several comments questioned the process that FDA used to develop the proposed rule. A number of comments expressed concern that health care practitioners other than physicians were not surveyed or otherwise consulted. Two comments indicated that a majority of pharmacists refer to prescription drug labeling at least once a day. The comments cited a survey finding that the sections most frequently referred to by pharmacists are, in descending order, ''Dosage and Administration,'' ''Adverse Reactions,'' ''Contraindications,'' ''Indications and Usage,'' ''Warnings and Precautions,'' and ''How Supplied/Storage and Handling.'' The comments urged FDA to consult with all relevant audiences to revise prescription drug labeling and labels.

FDA recognizes the important roles that health care practitioners other than physicians play in the health care delivery system and recognizes that prescription drug information is relied upon by health care practitioners other than physicians. The agency focused its research efforts on how physicians use labeling, because they are the principal intended audience (i.e., they use labeling for prescribing decisions). The agency also sought input from all interested parties in the development of the proposed rule, especially those whose use of labeling could be expected to impact patient safety. Panelists and participants in the 1995 public meeting included nurse practitioners, pharmacists, and physician assistants. Their comments and observations directly contributed to refining the third version of FDA's prototype into the version that was the basis for the proposed rule. Moreover, the agency has carefully reviewed and considered all comments received on the proposed rule, which included comments from a broad range of health care practitioners that rely on prescription drug labeling, and has determined the optimal ordering for labeling sections, as reflected in this final rule.

FDA notes that the sections most commonly referred to by pharmacists in the cited survey are the same as those most commonly referred to by physicians, although in a somewhat different rank order. FDA believes that, although the rank order of the sections is not identical for the two groups, the formatting improvements required by this final rule make the information in these sections readily accessible to all health care practitioners who use prescription drug labeling.

C. Highlights of Prescribing Information—General Comments

FDA proposed to require that prescription drug labeling for products described in proposed § 201.56(b)(1) (i.e., new and more recently approved prescription drug products) contain introductory prescribing information entitled ''Highlights of Prescribing Information'' (proposed §§ 201.56(d) and 201.57(a)).

(Comment 2) Comments expressed different opinions about the utility and patient care implications of Highlights. Physicians, pharmacists, other health care practitioners, health care advocacy groups, and professional societies and organizations representing health care practitioners expressed unequivocal enthusiasm about and uniform support for Highlights. Manufacturers, with some exceptions, were opposed, or strongly opposed, to the inclusion of Highlights.

Comments supporting Highlights stated that it would be an excellent vehicle for drawing attention to the most important information about a product, a useful and convenient source for quick reminder information in routine prescribing situations, and a useful vehicle to efficiently direct practitioners to the more detailed information in the FPI. Several comments stated that Highlights is probably the most important innovation in the proposed rule. One comment stated that Highlights is the element of the proposal that will most enhance the clinical utility of prescription drug labeling. Several comments stated that by making prescription drug labeling easier to navigate, Highlights would help to make labeling easier for patients and health care practitioners to understand.

Several comments endorsed the Highlights format as a means of making labeling information more accessible. Some comments stated that the proposed format for Highlights is a good design because it makes use of multiple formats (e.g., text, tables, bulleted lists) and bolded headings, which make the labeling information more accessible. One comment noted that, because Highlights contains pointers to the location of more detailed information in the FPI, the pointers will increase the likelihood that health care practitioners will refer to the FPI. The comment also stated that the user-friendly Highlights format would be likely to increase the frequency with which health care practitioners consult the labeling for drug information and would enhance their ability to use the information.

Comments opposing inclusion of Highlights stated that manufacturers would be forced to pick certain important warnings listed in the FPI for inclusion in Highlights and, because of space limitations, exclude other important information. These comments maintained that, by extracting from the FPI only selected portions of the information needed for safe and effective use, Highlights would omit important information and lack detail and context, and might, therefore, be misleading. They contended that these shortcomings might outweigh any convenience derived from condensing information into Highlights. One comment maintained that the FPI is itself a condensation of a complex body of information and that it is problematic and illogical to try to further condense the information from the FPI into Highlights.

Several comments from manufacturers stated that the limited content of Highlights is of concern because practitioners would have a tendency to rely only on the information in Highlights when making prescribing decisions, even though that information alone would not be an adequate basis for making such decisions. Some of these comments maintained that there is a lack of evidence to support the premise that Highlights will facilitate practitioners' access to more detailed information in the FPI. They asserted that there is a high likelihood that Highlights would be the only part of the labeling read by practitioners.

Another comment stated that, rather than requiring inclusion of Highlights in labeling, the agency and manufacturers should work together to make the FPI better.

FDA has determined that the Highlights provisions of the final rule are an essential element of the agency's efforts to improve the accessibility, readability, and usefulness of information in prescription drug labeling and reduce the number of

adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information. By means of focus group testing, a nationwide physician survey, and a public meeting, the agency carefully evaluated the drug information needs of physicians and ways to best address those needs in prescription drug labeling. Some of the principal findings were that: (1) The relative importance of information in labeling varies, (2) physicians typically refer to labeling to answer a specific question, (3) physicians have considerable difficulty locating the information they need to make prescribing decisions, and (4) physicians strongly prefer to have a separate introductory summary of the most important information contained in the full prescribing information, located at the beginning of labeling, to make it easier to find the information necessary to prescribe the drug safely and effectively (65 FR 81082 at 81083 through 81085; see also Ref. 11). Many of the comments submitted in response to the proposed rule concur with these findings, particularly those from health care practitioners and their organizations.

This preference for highlighting the most important information that is part of a larger body of information is consistent with good risk communication practices and with well-established cognitive principles. The agency employed these principles in designing Highlights.

For example, cognitive research has shown that, because there is a limit to the amount of information that an individual can hold in memory at one time, individuals tend to organize similar information into ''chunks'' to: (1) Increase the amount of available space in memory and (2) facilitate retrieval of information (Refs. 1 through 3). ''Chunking'' complex information into smaller, more manageable units makes it easier to remember and process information efficiently and effectively (decreases ''cognitive load'').

FDA research conducted during development of new rules for OTC drug labeling demonstrated that ''chunking'' information in a standardized format with graphic emphasis on the most important information helped individuals make correct product use decisions, decreased reading time, and increased the individuals' confidence in their ability to use that information (Ref. 4). This research supports the approach adopted in this final rule for prescription drug labeling.

In designing Highlights, the agency employed established techniques to enhance effective communication of large amounts of complex information. Highlights summarizes the information from the FPI that is most important for prescribing the drug safely and effectively and organizes it into logical groups, or ''chunks,'' to enhance accessibility, retention, and access to the more detailed information. This design, combined with the use of multiple formats (e.g., tables, bulleted lists) and graphic emphasis (e.g., bolded text), improves visual and cognitive access to the information so that practitioners can more easily find information, and improves recall of the information.

Importantly, Highlights must include identifying numbers indicating where in the FPI to find details of the information that is cited or concisely summarized in Highlights. In the final rule, FDA has revised proposed § 201.57(a)(17) (§ 201.56(d)(3) in the final rule) to require that any information referenced in Highlights, not just subheadings, be accompanied by the identifying number corresponding to the location of the information in the FPI. The agency believes that these identifying numbers will facilitate access to the detailed information in the FPI.

The Highlights design—a broad array of important information in a discrete, visually accessible location—also increases the variety of information that a practitioner is exposed to in a typical labeling referral. That is, the Highlights design increases the likelihood that practitioners will be exposed to and retain critical information about a drug in addition to the information that the practitioner sought in referring to the labeling, such as the recommended dose. The practitioner therefore is likely to know more about a drug after exposure to labeling with Highlights than after exposure to labeling without Highlights. In addition, by making labeling easier to use and an overall better source of drug information, the Highlights design is likely to increase the frequency with which practitioners rely on labeling for prescription drug information. In a survey regarding labeling for vaccines, 71 percent of physicians surveyed indicated that they would increase their use of labeling if a summary of prescribing information were included in labeling (65 FR 81082 at 81084). Highlights should result in health care practitioners being better informed about prescription drugs. Therefore, the agency concludes that prescription drug labeling with Highlights more effectively communicates drug information to prescribers than labeling without Highlights.

(Comment 3) Some comments stated that FDA should do additional testing to determine whether Highlights is necessary to accomplish FDA's goal of making information in prescription drug labeling more useful and accessible or whether the other proposed format changes, without Highlights (i.e., an index, reordering of the sections of the FPI, and enhanced formatting) would be adequate to accomplish the agency's goal. One comment requested that FDA evaluate whether simply reordering the sections of the prescribing information would be adequate to accomplish the agency's goal. Some comments stated that the agency should test whether the proposed format would change prescriber behavior as intended and lead to a reduction in medication errors.

The agency believes it is unnecessary to compare the prototype labeling with Highlights to the prototype labeling without Highlights (i.e., a version with a table of contents, reordered sections in the FPI, and enhanced graphics, or a version with only reordered sections and enhanced graphics). The requirements of this final rule are built on extensive testing conducted by FDA, established principles of cognitive processing, previous research conducted by FDA for OTC drug labeling, and evaluation of comments submitted in response to this proposal. FDA has determined that Highlights, because it will efficiently and effectively convey information about a drug product and will help to facilitate the transition to electronic labeling, is a vital component of the efforts to reduce the numbers of adverse reactions from medication errors due to misunderstood or incorrectly applied drug information.

(Comment 4) In the proposed rule, FDA specifically sought comment on whether, and under what circumstances, it might be inappropriate to include the proposed Highlights in the labeling of a particular drug or drug class.

The vast majority of comments supported Highlights for all products or no products. One comment stated that if the agency retains the requirement to include Highlights, all products required to have the new format should be required to have Highlights. One comment stated it would not be useful to include Highlights if the entire labeling is very short (e.g., one page).

The agency concludes that there should be no exceptions to the Highlights requirement for drugs subject to the new content and format requirements at §§ 201.56(d) and 201.57. The agency acknowledges that prescription drug labeling for some drugs may be very short and that this

may result in short Highlights. However, as discussed previously, the agency has determined that Highlights improves the usefulness, readability, and accessibility of information in prescription drug labeling and is consistent with good risk communication practices.

(Comment 5) Several comments stated that there should be more specific criteria for selecting information for inclusion in Highlights to ensure consistency for all drug products. These comments stated that, without specific criteria, the information in Highlights for different drugs within the same drug class may be different, and these differences could be used to the competitive advantage or disadvantage of some products. Some comments stated that the agency should designate the precise information that must be included in Highlights. One comment said that, for products with class labeling, FDA must designate which class labeling statements must be included in Highlights to ensure consistency among drugs in the class. Another comment stated that the relative importance of drug information, and, as a result, the basis for selecting information for inclusion in the section, can vary depending on a drug's indication. The comment maintained that Highlights would have to provide for differences in safety profiles for drugs with multiple indications and those that are used in different populations.

The agency believes that these concerns are not unique to Highlights. The agency agrees that, for a given drug, if there are significant differences in safety profiles or dosing considerations for different indications or populations, Highlights must reflect these differences. The agency also agrees that it is critical to ensure accuracy and consistency in the information included in Highlights because it contains a summary of the most important information for prescribing the drug safely and effectively.

In general, however, the agency believes that it would not be appropriate, or possible, to specify in the final rule the precise content of Highlights. Judgment will continue to be necessary to determine what information from the broad range of information necessary for the safe and effective use of the prescription drug appearing in the FPI must also appear in Highlights (e.g., differences in safety profiles or dosing considerations for differing indications or populations). However, because Highlights is a summary of the most important information for prescribing decisions and some comments expressed concerns about the difficulty involved in summarizing the complex and often lengthy information in the FPI (see e.g., comments 16, 23 and 27), the agency believes that it is essential for FDA to review and approve most proposed changes to the information in Highlights. Accordingly, the agency is revising its regulations on supplements and other changes to an approved application. Under §§ 314.70(b)(2)(v)(C) and (c)(6)(iii), and 601.12(f)(1) and (f)(2)(i), applicants are required to obtain prior approval of any labeling changes to Highlights, except for editorial or similar minor changes, including removal of a listed section(s) from ''Recent Major Changes'' or a change to the most recent revision date of the labeling. Sections 314.70(d)(2)(x) and 601.12(f)(3)(i)(D) allow these editorial and similar minor changes in the labeling to be reported in an annual report.

In addition, as noted, the agency is making available guidance to assist manufacturers and FDA reviewers in developing prescription drug labeling. This guidance addresses, among other things, how to select information for inclusion in Highlights (section IV of this document).

In some instances, a statement for a drug or class of drugs is currently required by regulation to be included in a specific section of prescription drug labeling (e.g., § 201.21). In these cases, when converting labeling to the new format, the statements must be included in the corresponding section in the new format (e.g., a statement required to be included in the ''Boxed Warning'' section in the old format must be included in the ''Boxed Warning'' section in the new format). However, some statements are currently required to be included in labeling sections that have been altered or eliminated by this final rule. In these instances, the statements must be located in the FPI as outlined in table 6.

TABLE 6.—LOCATION OF STATEMENTS REQUIRED TO BE INCLUDED IN LABELING

Location—Old Format	Location—New Format
Warnings	Warnings and Precautions
Precautions (General)	Warnings and Precautions
Precautions (Drug interactions)	Drug Interactions
Precautions (Specific Populations)	Use in Specific Populations
Precautions (Information for patients)	Patient Counseling Information
How Supplied (or after How Supplied)	How Supplied/Storage and Handling

Where statements are required in labeling but not in a specific labeling section, the agency may specify the location in the FPI for the statements for the drug or class of drugs to ensure consistency within drug classes. Whether a specific statement required by regulation must appear in Highlights will be determined by the agency.

(Comment 6) Several comments stated that Highlights should mention the drug's therapeutic or pharmacologic class. They maintained that this information is informative to practitioners when the drug is a member of an established class because it puts the drug in a context with other therapies and helps prevent duplicative therapy.

The agency agrees that information about a drug's therapeutic or pharmacologic class is important and appropriate for inclusion in Highlights. If a drug is a member of an established therapeutic or pharmacologic class, the identity of that class can provide a practitioner with important information about what to expect from that product and how it relates to other therapeutic options. The agency also agrees with the comment that making the identity of a drug's class more prominent could reduce the likelihood of prescribers placing a patient on more than one therapy within the same class when such use would not be appropriate.

The agency believes that information about drug class is an important supplement to the information contained in a drug's ''Indications and Usage'' section and should be placed under that heading in Highlights. Accordingly, the agency has revised proposed § 201.57(a)(6) to require that when a drug is a member of an established pharmacologic class, the class must be identified in the ''Indications and Usage'' section in Highlights.

(Comment 7) One comment stated that Highlights should also include information about managing drug

overdose (recommended a new section entitled ''Toxicity and Overdose'') and characteristics by which a tablet can be identified (color, markings, shape, etc.).

The agency acknowledges the importance of information about managing drug overdose and characteristics by which a tablet can be identified and took care to make this information prominent in the FPI. However, space for Highlights is limited and the agency has made judgments about which information is most important for safe and effective use and thus must appear in Highlights. The agency has concluded that information about managing overdose or product identification characteristics (except scoring) will not be required in Highlights. The agency has retained scoring in Highlights because this information is needed to appropriately tailor a dose for some patients (e.g., a patient is unable to take two tablets of a drug because of a particular side effect, but is able to take one-and-one-half tablets).

(Comment 8) One comment stated that the information presented in Highlights should be in bulleted format to the extent possible to avoid redundancy with the information in the FPI.

FDA agrees that information presented in Highlights, not otherwise required to be bulleted under § 201.57(d)(4), should be succinctly summarized and in a format (e.g., bulleted) that calls attention, and provides easy access, to the more detailed information in the FPI. Highlights is not a verbatim repetition of selected information contained in the FPI.

(Comment 9) One comment requested that the sections in Highlights be reordered to lend more prominence to risk information. The comment stated that all risk information, including contraindications and drug interactions, should be placed before the ''Dosage and Administration'' and ''How Supplied'' sections.

The order of the sections in Highlights tracks the order of the corresponding sections in the FPI. The agency believes the order of information in Highlights must be consistent with the FPI so that practitioners can efficiently navigate from Highlights to the corresponding section of the FPI. As discussed in more detail in the preamble to the proposed rule (65 FR 81082 at 81084), the revised order of the sections in the FPI was based on extensive focus group testing and surveys of physicians to determine which sections they believe are most important to prescribing decisions and which sections they reference most frequently.

The agency believes that the order of information in Highlights required by the final rule gives sufficient prominence to risk information. The agency also believes that the formatting requirements, the one-half page length restriction for Highlights (excluding space for a boxed warning, if one is required) (§ 201.57(d)(8)), and the limitations on the amount of information that can be included in Highlights will ensure that all the information in Highlights has adequate prominence and is visually accessible.

(Comment 10) One comment expressed concern about the implications of Highlights for FDA's initiative to improve pregnancy labeling. The comment stated that the preliminary format FDA has discussed in public meetings (which would replace the pregnancy category designations) could not be readily condensed into an informative single sentence in Highlights. The comment suggested that electronic labeling could potentially solve this problem by linking to additional information about prescribing in specific patient populations and by linking to pregnancy registry databases and tertiary specialty texts as well.

The agency anticipates that the planned revisions to the requirements for the ''Pregnancy'' subsection of labeling are unlikely to affect the information in Highlights about use of drugs during pregnancy. The agency agrees that the electronic labeling initiative holds great promise for providing rapid access to related information of varying levels of complexity and detail, including information about drug exposure during pregnancy.

(Comment 11) Several comments recommended that there be an educational campaign in conjunction with the publication of the final rule to ensure that practitioners understand that Highlights contains only limited information and should not be relied on without reference to the FPI.

The agency agrees that there should be, and it plans to initiate, an educational campaign to familiarize health care practitioners with the new labeling format. The agency also agrees that an important component of the educational message should be that Highlights alone does not contain all the information FDA has determined is needed to use a drug safely and effectively.

D. Comments on Product Liability Implications of the Proposed Rule

In the proposal, FDA requested comments on the product liability implications of revising the labeling for prescription drugs.

(Comment 12) In comments, some manufacturers expressed concerns that, by highlighting selected information from the FPI to the exclusion of information not highlighted, they make themselves more vulnerable to product liability claims. Some of these comments also stated that the Highlights limitation statement, which states that Highlights does not contain all the information needed to prescribe a drug safely and effectively and that practitioners should also refer to the FPI, would not constitute an adequate legal defense in a case alleging failure to provide adequate warning of a drug's risks.

Based on the agency's research and analysis in developing the prototype labeling that was the basis for the proposed rule (see comment 2), the agency has concluded that a labeling format that includes Highlights is more effective than a format that omits Highlights. In response to the comments and as discussed in the response to comment 35, FDA has taken steps to enhance the prominence of the Highlights limitation statement. FDA believes the statement will be effective in reminding prescribers that the information in the Highlights should not be relied on exclusively in making prescribing decisions and that it is important to consult the more detailed information in the FPI. We also believe that this limitation statement will help to ensure that the labeling will be considered in its entirety in any product liability action. FDA acknowledges the comment's concerns and, as discussed more fully in response to comment 13, believes that under existing preemption principles such product liability claims would be preempted.

(Comment 13) Some comments stated that the new format requirements might have product liability implications for drugs that are not subject to the new requirements. These comments expressed concern that labeling in the old format might be characterized by plaintiffs as inferior to labeling in the new format and, as a result, could be used as evidence that a manufacturer did not provide adequate warnings. They requested that the agency state in the final rule that FDA approval of labeling, whether it be in the old or new format, preempts conflicting or contrary State law, regulations, or decisions of a

court of law for purposes of product liability litigation.

FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law. Indeed, the Department of Justice (DOJ), on behalf of FDA, has filed a number of amicus briefs making this very point. In order to more fully address the comments expressing concern about the product liability implications of revising the labeling for prescription drugs, we believe it would be useful to set forth in some detail the arguments made in those amicus briefs. The discussion that follows, therefore, represents the government's long standing views on preemption, with a particular emphasis on how that doctrine applies to State laws that would require labeling that conflicts with or is contrary to FDA-approved labeling.

Under the act, FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading. Under the act and FDA regulations, the agency makes approval decisions based not on an abstract estimation of its safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (21 U.S.C. 355(d)). FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance. The centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use. FDA continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate.

Changes to labeling typically are initiated by the sponsor, subject to FDA review, but are sometimes initiated by FDA. Under FDA regulations, to change labeling (except for editorial and other minor revisions), the sponsor must submit a supplemental application fully explaining the basis for the change (§§ 314.70 and 601.12(f) (21 CFR 314.70 and 601.12(f))). FDA permits two kinds of labeling supplements: (1) Prior approval supplements, which require FDA approval before a change is made (§§ 314.70(b) and 601.12(f)(1)); and (2) ''changes being effected'' (CBE) supplements, which may be implemented before FDA approval, but after FDA notification (§§ 314.70(c) and 601.12(f)(2)). While a sponsor is permitted to add risk information to the FPI without first obtaining FDA approval via a CBE supplement, FDA reviews all such submissions and may later deny approval of the supplement, and the labeling remains subject to enforcement action if the added information makes the labeling false or misleading under section 502(a) of the act (21 U.S.C. 352). Thus, in practice, manufacturers typically consult with FDA prior to adding risk information to labeling. As noted in response to comment 5, however, a sponsor may not use a CBE supplement to make most changes to Highlights.

Since the proposed rule was published, FDA has learned of several instances in which product liability lawsuits have directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the act. In one case, for example, an individual plaintiff claimed that a drug manufacturer had a duty under California State law to label its products with specific warnings that FDA had specifically considered and rejected as scientifically unsubstantiated.[4] In some of these cases, the court determined that the State law claim could not proceed, on the ground that the claim was preempted by Federal law,[5] or was not properly before the court by operation of the doctrine of primary jurisdiction.[6] In some cases, however, the court has permitted the claim to proceed.[7]

State law actions can rely on and propagate interpretations of the act and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate. For example, courts have rejected preemption in State law failure-to-warn cases on the ground that a manufacturer has latitude under FDA regulations to revise labeling by adding or strengthening warning statements without first obtaining permission from FDA. (*See, e.g., Eve* v. *Sandoz Pharm. Corp.*, 2002 U.S. Dist. LEXIS 23965 (S.D. In. Jan. 28, 2002); *Ohler* v. *Purdue Pharma, L.P.*, 2002 U.S. Dist. LEXIS 2368 (E.D. La. Jan. 22, 2002); *Motus* v. *Pfizer Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000); *Bansemer* v. *Smith Labs., Inc.*, 1988 U.S. Dist. LEXIS 16208 (E.D. Wis. Sept. 12, 1988); *McEwen* v. *Ortho Pharm Corp.*, 528 P.2d 522 (Ore. 1974).) In fact, the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act. A manufacturer may, under FDA regulations, strengthen a labeling warning, but in practice manufacturers typically consult with FDA before doing so to avoid implementing labeling changes with which the agency ultimately might disagree (and that therefore might subject the manufacturer to enforcement action).

Another misunderstanding of the act encouraged by State law actions is that FDA labeling requirements represent a minimum safety standard. According to many courts, State law serves as an appropriate source of supplementary safety regulation for drugs by encouraging or requiring manufacturers to disseminate risk information beyond that required by FDA under the act. (*See, e.g., Brochu* v. *Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981); *Salmon* v. *Parke-Davis and Co.*, 520 F.2d 1359 (4th Cir. 1975); *Caraker* v. *Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018 (S.D. Ill.

[4] *Dowhal* v. *SmithKline Beecham Consumer Healthcare*, 2002 Cal. App. LEXIS 4384 (Cal. Ct. App. 2002), reversed, 2004 Cal. LEXIS 3040 (Cal. April 15, 2004).

[5] *E.g., Ehlis* v. *Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002), *aff'd on other grounds*, 367 F.3d 1013 (8th Cir. 2004).

[6] *E.g., Bernhardt* v. *Pfizer, Inc.*, 2000 U.S. Dist. LEXIS 16963 (S.D.N.Y. Nov. 16, 2000). This doctrine allows a court to refer a matter to an administrative agency for an initial determination where the matter involves technical questions of fact and policy within the agency's jurisdiction. If a court finds that the agency has primary jurisdiction, the court stays the matter and instructs the plaintiff to initiate an action with the agency. *See, e.g., Israel* v. *Baxter Labs., Inc.*, 466 F.2d 272, 283 (D.C. Cir. 1972); see also 21 CFR 10.60.

[7] *Dowhal* v. *SmithKline Beecham Consumer Healthcare*, 2002 Cal. App. LEXIS 4384 (Cal. Ct. App. 2002), *reversed*, 2004 Cal. LEXIS 3040 (Cal. April 15, 2004); *Bernhardt* v. *Pfizer, Inc.*, 2000 U.S. Dist. LEXIS 16963 (S.D.N.Y. November 16, 2000); *Motus* v. *Pfizer, Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000), summary judgment granted, 196 F. Supp. 2d 984, 986 (C.D. Cal. 2001), aff'd, 2004 U.S. App. LEXIS 1944 (9th Cir. February 9, 2004); *In re Paxil Litigation*, 2002 U.S. Dist. LEXIS 16221 (C.D. Cal. August 16, 2002), transferred, 296 F. Supp. 2d 1374 (J.P.M.L. 2003).

2001); *Mazur* v. *Merck & Co., Inc.*, 742 F. Supp. 239 (E.D. Pa. 1990); *In re Tetracycline Cases*, 747 F. Supp. 543 (W.D. Mo. 1989).) In fact, FDA interprets the act to establish both a ''floor'' and a ''ceiling,'' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading. Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.

State law requirements can undermine safe and effective use in other ways. In the preamble accompanying the proposal, FDA noted that liability concerns were creating pressure on manufacturers to expand labeling warnings to include speculative risks and, thus, to limit physician appreciation of potentially far more significant contraindications and side effects (65 FR 81082 at 81083). FDA has previously found that labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to ''lose its significance'' (44 FR 37434 at 37447, June 26, 1979). Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health. (See section X of this document.) Similarly, State-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the act. (*See, e.g., Dowhal* v. *SmithKline Beecham Consumer Healthcare*, 2002 Cal. App. LEXIS 4384 (Cal. Ct. App. 2002) (allowing to proceed a lawsuit involving a California State law requiring warnings in the labeling of nicotine replacement therapy products that FDA had specifically found would misbrand the products under the act), reversed, 2004 Cal. LEXIS 3040 (Cal. April 15, 2004).)

State law actions also threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public—the central role of FDA—sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief—including the threat of significant damage awards or penalties—that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose ''defensive labeling'' to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments.

FDA has previously preempted State law requirements relating to drugs in rulemaking proceedings. For example:

- In 1982, FDA issued regulations requiring tamper-resistant packaging for OTC drugs. In the preamble accompanying the regulations, FDA stated its intention that the regulations preempt any State or local requirements that were ''not identical to * * * [the rule] in all respects'' (47 FR 50442 at 50447, November 5, 1982).
- In 1986, FDA issued regulations requiring aspirin manufacturers to include in labeling a warning against use in treating chicken pox or flu symptoms in children due to the risk of Reye's Syndrome. In the accompanying preamble, FDA said the regulations preempted ''State and local packaging requirements that are not identical to it with respect to OTC aspirin-containing products for human use'' (51 FR 8180 at 8181, March 7, 1986).
- In 1994, FDA amended 21 CFR 20.63 to preempt State requirements for the disclosure of adverse event-related information treated as confidential under FDA regulations (59 FR 3944, January 27, 1994). (See also 47 FR 54750, December 3, 1982) (''FDA believes that differing State OTC drug pregnancy-nursing warning requirements would prevent accomplishment of the full purpose and objectives of the agency in issuing the regulation and that, under the doctrine of implied preemption, these State requirements are preempted by the regulation as a matter of law.'')

As noted previously, DOJ has made submissions to courts in a number of cases in which private litigants asserted a State law basis for challenging the adequacy of risk information provided by manufacturers for drugs in accordance with FDA requirements under the act. In each case, DOJ argued that the doctrine of preemption precluded the plaintiff's claim from proceeding.[8] The practice of addressing conflicting State requirements through participation in litigation (including product liability cases) in which the Government is not a party is not new. For example, DOJ participated on FDA's behalf in favor of pre-emption in *Jones* v. *Rath Packing Company*, 430 U.S. 519 (1977), *Grocery Manufacturers of America, Inc.* v. *Gerace*, 755 F.2d 993 (2d Cir. 1985), *Eli Lilly & Co., Inc.* v. *Marshall*, 850 S.W.2d 155 (Tex. 1993), and *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 352–53 (2001). FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated. In such cases, including the statement in labeling or advertising would render the drug misbranded under the act (21 U.S.C. 352(a) and (f)). The agency believes that State law conflicts with and stands as an obstacle to achievement of the full objectives and purposes of Federal law if it purports to preclude a firm from including in labeling or advertising a statement that is included in prescription drug labeling. By complying with the State law in such a case and removing the statement from labeling, the firm would be omitting a statement required under § 201.100(c)(1) as a condition on the exemption from the requirement of adequate directions for use, and the omission would misbrand the drug under 21 U.S.C. 352(f)(1). The drug might also be misbranded on the ground that the omission is material within the meaning of 21 U.S.C. 321(n) and makes the labeling or advertising misleading under 21 U.S.C. 352(a) or (n).

Consistent with its court submissions and existing preemption principles, FDA believes that at least the following

[8] The DOJ submissions in these cases relied on the doctrine of implied preemption or primary jurisdiction. Although the act itself contains no general express pre-emption provision for drugs, a provision of legislation amending the drug provisions addresses the relationship of the legislation to State law. Section 202 of the Drug Amendments of 1962 (Public Law 87-781, Title II, section 202, 76 Stat. 793 (October 10, 1962)) provides: ''Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.'' The existence of a legislative provision addressing pre-emption does not bar the operation of ordinary principles of implied preemption (*Geier* v. *American Honda Motor Co., Inc.*, 529 U.S. 861, 869 (2000)).

claims would be preempted by its regulation of prescription drug labeling: (1) Claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling; (2) claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug's sponsor has used Highlights consistently with FDA draft guidance regarding the ''brief summary'' in direct-to-consumer advertising (''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements,'' 69 FR 6308 (February 2004)) (see comment 112); (3) claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule, including § 201.57(c)(5) (requiring that contraindications reflect ''[k]nown hazards and not theoretical possibilities'') and (c)(7); (4) claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn); (5) claims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising; and (6) claims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's label (unless FDA has made a finding that the sponsor withheld material information relating to the statement). Preemption would include not only claims against manufacturers as described above, but also against health care practitioners for claims related to dissemination of risk information to patients beyond what is included in the labeling. (See, e.g., *Bowman* v. *Songer*, 820 P.2d 1110 (Col. 1991).)

FDA recognizes that FDA's regulation of drug labeling will not preempt all State law actions. The Supreme Court has held that certain State law requirements that parallel FDA requirements may not be preempted (*Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 495 (1996) (holding that the presence of a State law damages remedy for violations of FDA requirements does not impose an additional requirement upon medical device manufacturers but ''merely provides another reason for manufacturers to comply with * * * federal law''); id. at 513 (O'Connor, J., concurring in part and dissenting in part); id)). *But see Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 352–53 (2001) (holding that ''fraud on the FDA'' claims are preempted by Federal law); 21 U.S.C. 337(a) (restricting the act enforcement to suits by the United States); *In re Orthopedic Bone Screw Prods. Liability Litig.*, 159 F.3d 817, 824 (3d Cir. 1998) (''Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA [Medical Device Amendments]'').

E. Highlights—Comments on Specific Provisions

The agency received comments on the following provisions of the proposed rule relating to the content of Highlights:

• *Drug names, dosage form, route of administration, and controlled substance symbol (proposed § 201.57(a)(1))*

In proposed § 201.57(a)(1), FDA specified the information concerning the identity of the product that would be included at the beginning of Highlights.

(Comment 14) One comment recommended that this information be moved above the title ''Highlights of Prescribing Information'' in Highlights.

The agency does not agree that the information required by § 201.57(a)(1) should be placed above the title ''Highlights of Prescribing Information.'' The agency believes that the title of each of the three major portions of prescription drug labeling (''Highlights of Prescribing Information,'' ''Full Prescribing Information: Contents,'' and ''Full Prescribing Information'') should be placed at the beginning of the corresponding information so that the title is readily apparent to users.

• *Inverted black triangle (proposed § 201.57(a)(2))*

FDA proposed to require that products that contain a new molecular entity, new biological product, or new combination of active ingredients have in their labeling an inverted black triangle to indicate that the drug or drug combination had been approved in the United States for less than 3 years (proposed § 201.57(a)(2)). This proposal also applied to marketed products approved for a new indication, for use by a new route of administration, or with a novel drug delivery system.

(Comment 15) Several comments opposed, or expressed reservations about, the use of an inverted black triangle to identify a product, indication, or dosage form that has been approved for less than 3 years. There were concerns that the symbol is not universally understood and could therefore be confusing to practitioners. One comment stated that use of icons to convey public health information has historically been unsuccessful. Some of the comments stated that if the inverted black triangle were retained, the agency would need to conduct an extensive educational campaign to educate practitioners about its meaning and purpose. Some comments also expressed the concern that labeling containing the symbol could be in circulation much longer than 3 years after approval, which would undermine the significance of the symbol. One comment stated that the symbol implies, without basis, that newer drugs are inherently less safe than older drugs. Some comments stated that the criteria for when a new indication would extend the time for which a product must have the inverted black triangle are not clear.

Two comments stated that a bold approval date might be more informative than the inverted black triangle. Another comment recommended using the designation ''New-Rx'' to identify a product that has been approved for less than 3 years.

Other comments expressed strong support for the inverted black triangle as a mechanism to prompt practitioners to more carefully scrutinize the labeling of newer products and more diligently report adverse events. The comments maintained that use of the inverted black triangle could lead to earlier detection of rare, serious adverse reactions and, thus, could potentially save lives. One comment suggested extending the time that the inverted black triangle would be required to 5 years.

The agency has reconsidered its proposal to require use of the inverted black triangle to identify products that have been marketed for less than 3 years. The agency continues to believe strongly in the goals of the inverted black triangle—to help ensure that prescribers use a product with particular care during its initial years of marketing and to make prescribers more diligent in reporting suspected adverse reactions for newer products. However, the agency agrees with comments that, in prescription drug labeling, the inverted black triangle is not universally

understood, could be confusing to the prescriber (even with a concerted educational effort) and therefore may not serve its intended purpose. The agency acknowledges that the recommended ''New-Rx'' designation may be more informative than the inverted black triangle, but is concerned that the ''New-Rx'' designation might also be confusing because practitioners are not familiar with it.

The agency agrees with comments that use of the initial date of approval in the United States would be a better mechanism than the inverted black triangle to call attention to the relative newness of a product. Therefore, the final rule requires that Highlights include the year in which a drug was initially approved in the United States. Highlights must contain the phrase ''Initial U.S. Approval'' followed by the four-digit year of initial approval in bold face type (§ 201.57(a)(3) and (d)(5)). Because this statement takes up more space than the proposed inverted black triangle, the final rule requires that the statement be placed on its own line directly below the established name of the product (proper name of the product for biological products) rather than on the same line as the proprietary name (§ 201.57(a)(3)).

In contrast to the proposed rule, the final rule does not require identification of the initial date of U.S. approval of a new indication for a new population, new route of administration, or novel delivery system. The agency agrees with comments that expressed concerns that also requiring the inverted black triangle for new indications, routes of administration, and novel delivery systems could diminish the significance of the inverted black triangle and could be confusing to practitioners. Similarly, the agency believes that referring to multiple dates, including the date of initial approval of a new indication, new route of administration, or a novel delivery system for a drug would be confusing and would diminish the significance of these references. The agency is, therefore, limiting identification of the initial date of U.S. approval to new molecular entities, new biological products, or new combinations of active ingredients because this is sufficient to accomplish the goals of increasing prescriber vigilance and reporting of suspected adverse reactions when using newer products.

The agency believes the date of initial U.S. approval will continue to be informative throughout a product's life cycle. Although the agency does not subscribe to the view that newer drugs are inherently less safe, it does believe that alerting a practitioner to the fact that a drug has been marketed for an extended period could provide some added assurance about the drug's safety margin based on cumulative, safe experience with the product. Therefore, the requirement to include the initial date of U.S. approval in Highlights will not lapse 3 years after approval of the product for marketing.

• *Boxed warnings or contraindications (proposed § 201.57(a)(4))*

FDA proposed to require that the full text of boxed warning(s) or contraindication(s) required by proposed § 201.57(c)(1) be included in Highlights unless the boxed warning was longer than 20 lines, in which case a summary of the contents of the boxed warning would be required (proposed § 201.57(a)(4)). The agency specifically sought comment on whether the full text of a boxed warning should be included in Highlights, regardless of length.

(Comment 16) Some comments supported the proposed 20-line limitation on the length of a boxed warning in Highlights. Other comments recommended that the boxed warning in Highlights always be a summarized version of the boxed warning in the FPI. Others expressed concern that summarizing boxed warnings might result in the omission of key information or lead to misinterpretations of the warning. They stated that the boxed warning is already succinct and the language is carefully negotiated with FDA and, therefore, that the boxed warning should always be included in its entirety in Highlights.

The agency has retained the 20-line length limitation on boxed warnings in Highlights. The agency believes that 20 lines is sufficient space to alert practitioners to the critical risk information contained in a boxed warning and to refer them to more detailed information in the FPI (complete boxed warning and other sections in the FPI).

The agency agrees with the comments that stated that manufacturers should always be required to present summarized boxed warning information in Highlights. The agency has determined that information from boxed warnings can readily be condensed without omitting critical risk information. The agency believes a summarized boxed warning in Highlights, with references to more detailed information in the FPI, is the most effective way to communicate critical risk information to practitioners. The agency has revised proposed § 201.57(a)(4) to require that boxed warnings be summarized concisely in Highlights.

(Comment 17) Several comments stated that inclusion of the full boxed warning in Highlights and in the FPI was needlessly duplicative and recommended that the boxed warning be included in only one location. One comment maintained the boxed warning should appear only in the ''Warnings and Precautions'' section in the FPI.

As discussed in the response to the previous comment, the boxed warning in Highlights is required to be a summary of the complete boxed warning in the FPI. Thus, the boxed warning in Highlights will not duplicate the boxed warning in the FPI. The agency believes that a summarized boxed warning must be included in Highlights to ensure that practitioners are exposed to critical information at the beginning of prescription drug labeling and that the complete boxed warning is needed to expand on the summary in Highlights.

The agency does not agree that the complete boxed warning in the FPI should be placed in the ''Warnings and Precautions'' section rather than at the beginning of the FPI. Placement of the complete boxed warning at the beginning of the FPI, where it can be easily located, is consistent with good risk communication practices, as well as health care practitioner preferences articulated in public comments and FDA's physician surveys and focus group research.

• *Recent labeling changes (proposed § 201.57(a)(5))*

FDA proposed to require in Highlights a heading entitled ''Recent Labeling Changes'' that identifies the sections in the FPI that contain recent FDA-approved or authorized substantive labeling changes (proposed § 201.57(a)(5)).

(Comment 18) In general, comments supported the addition of a ''Recent Labeling Changes'' heading to labeling and many comments thought the information would be very useful to practitioners. However, one comment recommended that the proposed heading ''Recent Labeling Changes'' be changed to ''Sections Revised'' to accommodate changes that, although no longer truly recent, would be important to call to the attention of practitioners for an extended period of time (e.g., through multiple labeling revisions). Another comment recommended that the heading be changed to ''Last Labeling Revisions'' to accommodate changes that could no longer reasonably be considered recent (e.g., a situation in which years elapse between labeling changes).

The agency agrees that the proposed heading should be changed to better reflect the function of including the information. Thus, the final rule requires the heading ''Recent Major Changes'' (§ 201.57(a)(5)). FDA believes that it is important to characterize the changes listed under the heading as both ''recent'' and ''major'' to draw attention to the relative newness of the changes and to let practitioners know that identified changes are significant to clinical use of the drug (i.e., substantive), and not merely editorial.

(Comment 19) In the proposal, the agency specifically sought comment on whether there should be a time limit by which information under the proposed heading (now ''Recent Major Changes'') must be removed. Some comments supported a 1-year time limit for inclusion of information under the proposed heading. Other comments stated that there should be no fixed time limit for removal of information identified as a recent labeling change. These comments expressed concern that requiring labeling to be revised for the sole purpose of removing information from under the heading would lead to unnecessary expense, and that such information be removed at the next substantive labeling revision. Other comments stated that no time limit should be imposed for removal, but that removal should occur at the first convenient opportunity after 1 year from the date of the labeling change. Another comment stated that information should remain under the ''Recent Major Changes'' heading for 1 to 3 years after the change to keep practitioners up-to-date on labeling changes.

The agency agrees that, although there should not be a rigid time limit for removal of information from ''Recent Major Changes,'' the information should not remain in Highlights indefinitely. The purpose of the heading is to alert practitioners to recent substantive labeling changes. The agency is concerned that the information might be ignored by practitioners if it often identifies changes that are no longer recent. The agency will, therefore, require that labeling changes identified under this heading be deleted at the first reprinting of the labeling after the change has been in labeling for 1 year. This requirement should ensure that labeling changes identified under the ''Recent Major Changes'' heading are current without imposing unnecessary costs on industry by requiring labeling revisions solely for the purpose of removing the information.

(Comment 20) Because there could be multiple changes to labeling in a calendar year, some comments recommended that each change appearing under ''Recent Major Changes'' be dated in a month/year format so that practitioners can readily identify the most recent changes.

The agency agrees that it would be useful to date the labeling changes identified under this heading. The agency has, therefore, revised proposed § 201.57(a)(5) to require that sections of prescription drug labeling listed under ''Recent Major Changes'' be followed by the month and year in which the change was incorporated in the labeling.

(Comment 21) One comment recommended that the rule specify that changes should be listed chronologically beginning with most recent.

The agency does not agree. Where there are multiple recent changes and those changes appear in more than one section, to avoid confusion, the order in which the sections are listed under ''Recent Major Changes'' should be consistent with the order of the sections in the FPI. FDA has revised proposed § 201.57(a)(5) accordingly.

(Comment 22) Some comments requested that the agency clarify how it will determine whether a labeling change is substantive and thus required to be included under ''Recent Major Changes.''

The agency recognizes that a product may have a large number of labeling changes ranging from inclusion of very important new risk information to typographical or editorial changes. Identifying all these changes under ''Recent Major Changes'' would obscure the most significant changes and would not be informative for practitioners. Therefore, the agency has revised proposed § 201.57(a)(5) to require that only substantive labeling changes in the ''Boxed Warning,'' ''Indications and Usage,'' ''Dosage and Administration,'' ''Contraindications,'' and ''Warnings and Precautions'' sections be included under ''Recent Major Changes.'' These would include only those changes that are significant to the clinical use of the drug and, therefore, have significant clinical implications for practitioners (i.e., substantive changes). Thus, ''Recent Major Changes'' would not include any changes in the sections subject to this requirement that are typographical or editorial.

• *Indications and usage (proposed § 201.57(a)(6))*

FDA proposed to require that Highlights include an ''Indications and Usage'' heading that contains a concise statement of each of the product's indications, as specified in proposed § 201.57(c)(2), with any appropriate subheadings (proposed § 201.57(a)(6)). This information would include major limitations of use (e.g., particular subsets of the populations, second line therapy status). The agency specifically sought comment on whether the information required under the ''Indications and Usage'' heading of Highlights should be presented verbatim from the FPI or summarized in a bulleted format.

(Comment 23) Several comments stated that it was important to reproduce the ''Indications and Usage'' section verbatim to prevent confusion or misinterpretations. Other comments maintained that there should be flexibility to reproduce the information in the ''Indications and Usage'' section verbatim or summarize it in a bulleted format, depending on factors such as the amount of information in the ''Indications and Usage'' section and whether the information can be summarized and still effectively communicate what a practitioner should know about a drug's indications. Other comments recommended that there be bulleted summaries of the indications in all cases. One of these comments suggested that each bullet be preceded by an index number that corresponds with the index number of the full description of the indication in the FPI.

The agency has determined that the amount of information that must be included in Highlights from the ''Indications and Usage'' section of the FPI will vary. In most cases, the ''Indications and Usage'' section can be readily condensed (e.g., bulleted format) to provide prescribers with an accurate and informative summary, even if there is space available in Highlights to reproduce the ''Indications and Usage'' section from the FPI in its entirety (i.e., the one-half page limit requirement would not be exceeded).

The agency recognizes that for some products with many indications, it may not be possible to limit Highlights to one-half page in length (§ 201.57(d)(8)), even using a summarized version of the ''Indications and Usage'' section. In such cases, FDA may waive the one-half page requirement and approve the labeling with slightly longer Highlights (see comment 104).

• *Dosage and administration (proposed § 201.57(a)(7))*

FDA proposed that Highlights include, under a ''Dosage and Administration'' heading, the most important information in the ''Dosage and Administration'' section of the FPI (proposed § 201.57(a)(7)).

(Comment 24) One comment recommended that ''Dosage and Administration'' in Highlights include,

in addition to the usual recommended doses, a range of doses known to be effective, and in particular, doses lower than the usual recommended doses. The comment stated that 76.2 percent of all adverse reactions are dose-related and many patients respond to lower doses than those recommended in labeling. Therefore, the comment suggested, lower doses may prevent adverse reactions.

FDA agrees that it is important to include in labeling the full range of doses that FDA has concluded are effective. The agency has revised proposed § 201.57(a)(7) to clarify the range of doses to be included under the ''Dosage and Administration'' heading in Highlights.

(Comment 25) Several comments supported tabular presentation of dosage and administration information in Highlights. One comment proposed the use of a titration dose column (a visual tool to depict a drug's titration regimen) in Highlights for drugs for which titration is relevant. One comment maintained that the dosage adjustment statement in the prototype that accompanied the proposed rule should be highlighted and enlarged.

FDA agrees with the comment that supported use of a tabular format for ''Dosage and Administration'' in Highlights. However, because a tabular format or a titration dose column may not be appropriate for all drug products, FDA is not requiring use of these formats under the ''Dosage and Administration'' heading.

With respect to highlighting and enlarging the dosage adjustment statement in the prototype, FDA believes that bolded type is sufficient to draw attention to particularly important dosage adjustment statements and that enlarging the statement is not necessary. Enlarging only dosage adjustment information in Highlights would make this information appear more significant than other information in Highlights, which would not be appropriate. Therefore, FDA is not requiring that dosage adjustment statements in Highlights be in larger font than other information in Highlights.

(Comment 26) One comment requested that when the labeling states that there may be a need for dosage adjustments in patients with renal or hepatic impairment, it also specify how to adjust the dose or dosing interval.

Highlights identifies important information about the need for dosage adjustments in specific populations and refers to the section of the FPI where more detailed information about how to adjust doses can be obtained. FDA believes that complete information about how to adjust dosages for various specific populations would in many cases require a great deal of space. Therefore, FDA is not requiring that such information be included in Highlights.

• *Warnings and precautions (proposed § 201.57(a)(10))*

FDA proposed to require that Highlights include, under a ''Warnings and Precautions'' heading, a concise summary of the most clinically significant aspects of the ''Warnings and Precautions'' section of the FPI (proposed § 201.57(a)(7)). The information chosen from the FPI would include those warnings and precautions that affect prescribing because of their severity and consequent influence on the decision to use the drug, because monitoring of them is critical to safe use of the drug, or because measures can be taken to prevent or mitigate harm.

(Comment 27) Some comments requested clarification of the scope of information to be included in Highlights under the ''Warnings and Precautions'' heading. Comments expressed concern that summarizing selected safety information from the ''Warnings and Precautions'' section of the FPI might cause some important safety information to be omitted from Highlights.

''Warnings and Precautions'' in Highlights serves to: (1) Identify the most clinically significant risks discussed in the ''Warnings and Precautions'' section in the FPI, (2) concisely summarize the salient features of those risks, and (3) direct the practitioner to the more detailed discussion of risks in the FPI. Information under the ''Warnings and Precautions'' heading in Highlights will typically include those risks that: (1) Affect decisions about whether to prescribe a drug, (2) require monitoring of patients to ensure safe use of the drug, or (3) require that measures be taken to prevent or mitigate harm. The agency has revised § 201.57(a)(10) to make clear the scope of information to include under this heading.

Because the risks identified under the ''Warnings and Precautions'' heading in Highlights will refer the prescriber to the full discussion in the ''Warnings and Precautions'' section of the FPI, the agency believes that important risk information will not be overlooked by practitioners.

(Comment 28) One comment stated that it would be misleading to include the most common adverse reactions under ''Warnings and Precautions'' in Highlights because the most common adverse reactions are not likely to be discussed in the ''Warnings and Precautions'' section of the FPI. Rather, they are more likely to be discussed in the ''Adverse Reactions'' section of the FPI. The comment recommended that the most common adverse reactions be listed under a separate section in Highlights immediately following the contact information for reporting suspected serious adverse reactions.

The agency agrees that it may be confusing to include under the ''Warnings and Precautions'' heading in Highlights information that is derived from both the ''Warnings and Precautions'' and ''Adverse Reactions'' sections of the FPI. The agency is, therefore, revising proposed § 201.57(a) by adding to Highlights a heading entitled ''Adverse Reactions'' (§ 201.57(a)(11)) that is required to follow the ''Warnings and Precautions'' section. Information under the ''Adverse Reactions'' heading must include: (1) A listing of the most frequently occurring adverse reactions identified in the ''Adverse Reactions'' section in the FPI and (2) contact information for reporting suspected adverse reactions. The sequence in which the information is presented in Highlights—the most frequently occurring adverse reactions followed by contact information for reporting suspected adverse reactions—is unchanged from the proposed rule.

(Comment 29) One comment requested clarification about whether only information that is supported by clinical data would be appropriate for inclusion in Highlights.

In most cases, the risk information in Highlights would be based on clinical data. However, risk information derived from animal data could be appropriate for inclusion in Highlights. For example, warnings about a drug's risks in pregnancy could be based entirely on animal data and might be appropriate for inclusion in Highlights. In such cases, Highlights must present only the clinically significant conclusions about risk in pregnancy (e.g., significant teratogen) and not include a discussion of the animal data that are the basis for the risk information presented.

• *ADR reporting contacts (proposed § 201.57(a)(11))*

FDA proposed (proposed § 201.57(a)(11)) to require that Highlights include, for drug products other than vaccines, a statement following the information under the ''Warnings and Precautions'' heading: ''To report SUSPECTED SERIOUS ADRs, call (*insert name of manufacturer*) at (*insert manufacturer's phone number*) or FDA's MedWatch at (*insert the current FDA MedWatch number*).'' For vaccines, the following statement would be required: ''To report

SUSPECTED SERIOUS ADRs, call (*insert name of manufacturer*) at (*insert manufacturer's phone number*) or VAERS at (*insert the current VAERS number*).'' The agency specifically requested comment on whether it is necessary to include a contact number for reporting suspected adverse reactions in both Highlights and the ''Warnings and Precautions'' section of the FPI.

(Comment 30) Some comments stated that the contact information should be in both Highlights and FPI to make it more convenient to access and increase the likelihood that practitioners will be prompted to report suspected adverse reactions. Other comments stated that it would not be necessary to include contact information in both places because prominent placement of the information in Highlights alone would be sufficient to encourage practitioners to report adverse reactions. Some comments agreed that one location would be sufficient, but because those comments also opposed inclusion of Highlights in labeling, they recommended including the contact information in the FPI. Other comments suggested locating the contact information at the beginning of the labeling or in a ''box'' to increase its prominence. One comment recommended that the information be included only once and in close proximity to the name and address of the manufacturer in the FPI. The comment maintained that it is not intuitive to look for adverse reaction reporting contact information under ''Warnings and Precautions.'' One comment objected to inclusion of any adverse reaction reporting contact information in labeling. That comment maintained that contact information is not prescribing information and thus not appropriate for inclusion in labeling and, moreover, that there is no evidence that inclusion of such information in labeling will facilitate reporting of adverse reactions.

The agency agrees with the comments that support inclusion of contact information for reporting adverse reactions only in Highlights. Because the contact information is featured prominently in Highlights—bolded and set apart from other information—the agency believes that this is sufficient to make practitioners aware of the appropriate contacts to report adverse reactions and to encourage them to report suspected adverse reactions. The agency also believes that as prescribers become familiar with the content of Highlights, they will become increasingly aware of and familiar with the location of the adverse reaction reporting contact information. The agency does not believe that also including contact information in the FPI, even if moved to the beginning of the FPI, would result in meaningfully expanding the number of practitioners who become aware of the contact information. Therefore repeating the contact information in the FPI would not have a meaningful effect on the extent to which practitioners report adverse events. The agency also does not believe that placing the contact information for reporting suspected adverse reactions only in the FPI would afford the information adequate prominence. Accordingly, the final rule was revised to delete the proposed requirement at § 201.57(c)(6)(v) that contact information for adverse reaction reporting be included in the ''Warnings and Precautions'' section in the FPI. The agency believes it is unnecessary to further increase the prominence of the adverse reaction reporting contact information. Its current location—immediately following the listing of the most common adverse reactions—is the appropriate location, and the bolding and use of capitalization are sufficient to call attention to the information and distinguish it from adjacent information.

The agency does not agree that the adverse reaction reporting contact information should be omitted from labeling because it is not considered prescribing information. Including adverse reaction reporting contact information in labeling enables practitioners to report adverse reactions to FDA promptly. The agency monitors these reports and analyzes the adverse reactions data to determine whether labeling revisions are necessary for safe and effective use.

(Comment 31) Some comments recommended that only the manufacturer's phone number be included in prescription drug labeling, while others agreed that including the MedWatch phone number is important because manufacturers' phone numbers are subject to change. One comment requested that a telephone number for the relevant FDA review division also be included. Two comments recommended including the manufacturer's Web site in the reporting contact information.

The agency agrees that it is important to include both the manufacturer's phone number and FDA's phone number for voluntary reporting of adverse reactions. The agency believes that providing practitioners two options for reporting adverse reactions will help ensure that they always have someone to contact about an adverse reaction. The agency believes it is not appropriate to also include the phone number of the FDA review division that approved the drug. FDA review divisions are not the initial point of contact for postmarketing adverse reaction reports; therefore, manufacturers and practitioners should not send these reports to the review divisions for processing. It is critical that these reports be directed to the location(s) in FDA that are responsible for receiving and processing these reports so that they are evaluated and analyzed in an appropriate manner.

The agency agrees with comments recommending that, in addition to their phone number, manufacturers include the direct link to the section of their Web site for voluntary reporting of adverse reactions. The agency has revised proposed § 201.57(a)(11) to require the address of the Web site, if one is available. The agency will not require that manufacturers create a Web site to meet this requirement.

The agency has also decided to require that the adverse reaction reporting contact information include the FDA Web site address for voluntary reporting of adverse reactions (currently, *http://www.fda.gov/medwatch* for drug products except vaccines and *http://www.fda.gov/vaers* for vaccines). This Web site has become an increasingly important source of adverse reaction reports. The agency has concluded that providing practitioners with the convenience of being able to submit an adverse reaction report electronically may encourage reporting of adverse reactions that might not otherwise be reported. Thus, the agency believes it is very important to require identification of this Web site address in labeling, in addition to the FDA telephone number.

(Comment 32) Two comments stated that all adverse reactions should be reported, and not just serious adverse reactions.

The agency agrees that practitioners should not be discouraged from reporting adverse reactions that might not be considered serious. Certain adverse reactions that are not considered serious can be clinically significant. Moreover, practitioners may not always be able to determine whether an adverse reaction meets the regulatory definition of serious (21 CFR 310.305(b), 21 CFR 312.32(a), 21 CFR 314.80(a), and 21 CFR 600.80(a)). Also, there are limitations on the extent to which a drug's risks (serious and nonserious adverse reactions) can be delineated before marketing. The agency, therefore, believes that practitioners should be encouraged to submit all suspected adverse reactions to the manufacturer or FDA, without regard to the seriousness

of the reaction, to facilitate faster and more accurate characterization of a drug's risk profile. Accordingly, FDA has revised proposed § 201.57(a)(11) to require that the statement for adverse reaction reporting contact information refer to all suspected adverse reactions, not just serious ones.

• *Drug interactions (proposed § 201.57(a)(12))*

FDA proposed to require that Highlights contain a ''Drug Interactions'' heading that would include, with any appropriate subheadings, a concise summary of the drug interaction information in the FPI (i.e., prescription or over-the-counter drugs or foods that interact in clinically significant ways with the product)(proposed § 201.57(a)(12)).

(Comment 33) Several comments strongly supported inclusion of ''Drug Interactions'' as a separate heading in Highlights. One comment recommended requiring separate subheadings for drug-drug, drug-food, drug-laboratory, and possibly drug-herbal interactions.

FDA will not require that ''Drug Interactions'' in Highlights include specific subheadings depending on whether the interaction is a drug-drug, drug-food, drug-herbal, or drug-laboratory interaction. Use of these subheadings is typically most appropriate when a drug has a large number of interactions in each of these categories. In other cases, it is unlikely to provide additional clarification sufficient to justify use of space for the subheadings.

• *Use in specific populations (proposed § 201.57(a)(13))*

FDA proposed to require that Highlights contain a ''Use in Specific Populations'' heading (proposed § 201.57(a)(13)). The agency proposed that this heading include, with any appropriate subheadings, a concise summary of information from this section of the FPI on any clinically important differences in response or use of the drug in specific populations.

(Comment 34) One comment requested that the agency specify that the pregnancy category designation be included under the ''Use in Specific Populations'' heading in Highlights because the pregnancy category quickly communicates whether use of a drug is appropriate during pregnancy.

The agency does not agree that pregnancy category designations are appropriate for inclusion in Highlights or that they are effective in quickly communicating whether use of a drug is appropriate during pregnancy. The agency believes the pregnancy category, in isolation, tends to oversimplify the risks of drugs in pregnancy and, as a result, may be confusing. Decisions about use of a drug in pregnancy should be based on careful consideration of available data, not simply on a reference to the pregnancy category.

• *Highlights limitation statement (proposed § 201.57(a)(15))*

FDA proposed (proposed § 201.57(a)(15)) to require that Highlights include the statement: ''These highlights do not include all the information needed to prescribe (*insert name of drug product*) safely and effectively. See (*insert name of drug product*)'s comprehensive prescribing information provided below.''

(Comment 35) Several comments recommended that the Highlights limitation statement be made more prominent by moving the statement to the beginning of Highlights. In addition, several comments recommended revisions to the language of the statement, such as including that practitioners ''must'' consult the comprehensive prescribing information, in addition to Highlights, to use a drug safely and effectively.

The agency agrees that it is important to emphasize to prescribers that Highlights does not include all the information needed to use a drug safely and effectively and that placement of the statement at the beginning of Highlights increases the prominence of this message. Therefore, FDA has revised proposed § 201.57(a)(15) to require that the statement appear at the beginning of Highlights (§ 201.57(a)(1)).

The agency does not agree, however, that it is necessary to revise the language of the Highlights limitations statement. Recognizing that FDA cannot require practitioners to consult the FPI, the agency believes that the language in this statement, with two minor editorial changes, very clearly states the limitations of Highlights.

F. Comments on the Index (Proposed § 201.57(b))

FDA proposed to require that prescription drug labeling for products described in proposed § 201.56(b)(1) (i.e., new and more recently approved prescription drug products) contain an index entitled ''Comprehensive Prescribing Information: Index'' (proposed § 201.57(b)). The index would list the subheadings required under proposed § 201.56(d)(1), if not omitted under proposed § 201.56(d)(3), and each optional subheading included in the FPI under proposed § 201.56(d)(5). Each subheading would be required to be preceded by its corresponding index number or identifier.

In the proposal, the agency specifically sought comment on whether it is necessary to require both an index and Highlights. As discussed in section II of this document, the agency has decided, on its own initiative, to change the title (now ''Full Prescribing Information: Contents'') to better reflect the function of this portion of the labeling.

(Comment 36) Most comments supported inclusion of an index (hereafter Contents). They maintained that Highlights alone cannot be relied upon to help locate all drug information in the FPI because Highlights is not comprehensive (Highlights includes information from only certain sections of the FPI). They stated that a table of contents is necessary to quickly and easily direct the reader to sections of the FPI that are not referred to in Highlights. Other comments stated that, despite the distinct purposes served by Highlights and Contents, the agency should consider consolidating them to save space. Some comments stated that there need not be both because they have similar functions and recommended that Contents be deleted if Highlights is retained. One comment recommended that prescription drug labeling include neither Contents nor Highlights. The comment stated that the reordered and reformatted FPI itself is adequate to facilitate practitioners' access to information in labeling.

FDA continues to believe that Highlights and Contents serve different purposes and has determined that both should be retained. Highlights presents a succinct summary of the information in the FPI that is most crucial for safe and effective use, with cross-references to direct prescribers to more details in the FPI. In contrast, Contents serves as a navigational tool that references all the sections and subsections in the FPI, some of which will not be referenced in Highlights. Therefore, the agency believes Contents has a unique and meaningful function in making information in the FPI accessible to practitioners.

In addition, Highlights and Contents both figure prominently in FDA's plans to convert prescription drug labeling to an electronic format (see section V of this document). The Contents will provide hyperlinks to all sections and subsections of the FPI, enabling practitioners to navigate the labeling more easily. Highlights will provide hyperlinks to the most frequently referenced and, typically, most important prescribing information, allowing rapid access to more detailed information on these critical topics.

(Comment 37) One comment recommended that, for sections of labeling that are omitted from the FPI

because they are not applicable, the agency consider including the section number and heading in Contents followed by the statement ''not applicable,'' rather than omitting the section number and heading. The comment noted that the prototype labeling in the proposed rule omitted a section and also omitted the listing of the section heading in Contents, and that this omission might confuse practitioners.

The purpose of Contents is to set forth the sections and subsections included in the FPI. For many drug products, some sections and subsections are not applicable (e.g., ''Drug Abuse and Dependence,'' ''References''). Currently, these sections are, in most cases, simply omitted from the labeling without discussion in accordance with former § 201.56(d)(3). The agency believes that this practice should continue, but recognizes that because identifying numbers are now required to be used for labeling of new and recently approved products, this practice may initially be confusing for some. The agency considered the comment's suggestion that the section identifying number and heading be included in Contents followed by the statement ''not applicable'' for labeling that omits a required section or subsection, but believes that this is not the best approach because of space considerations. Instead, to minimize any potential confusion regarding omitted sections, the agency has revised proposed § 201.56(d)(3) (designated in this final rule as § 201.56(d)(4)) to require in these cases that the Contents heading be followed by an asterisk and that the following statement be included at the end of Contents: ''* Sections or subsections omitted from the full prescribing information are not listed.''

In addition, for legal clarity, FDA revised proposed § 201.56(d)(3) and (e)(3) (§ 201.56(d)(4) and (e)(3) in this final rule) to make clear that clearly inapplicable sections, subsections, or specific information are omitted from labeling.

G. Full Prescribing Information—Comments on the Reorganization

FDA proposed to revise, for products described in proposed § 201.56(b)(1) (new and more recently approved prescription drug products), the content and format requirements of prescription drug labeling at then-current §§ 201.56(d) and 201.57. These revisions included, in proposed §§ 201.56(d) and 201.57(c), reordering the information in the FPI to make more prominent those sections that the agency identified (based on the physician surveys, focus groups, public comments, and its own experience) to be most important to, and most commonly referenced by, health care practitioners. For example, proposed § 201.57(c)(1) would require that any boxed warning(s) be the first substantive information to appear in the FPI, proposed § 201.57(c)(2) would require that the ''Indications and Usage'' section follow any boxed warnings in the FPI, and proposed § 201.57(c)(3) would require that the ''Dosage and Administration'' section follow the ''Indications and Usage'' section in the FPI.

(Comment 38) Virtually all the comments supported the proposed reordering of the FPI to give greater prominence to the sections that practitioners consider most important and refer to most often. Many comments agreed that the reordering, by better reflecting the way the information in the FPI is used, would make the FPI more useful and accessible to practitioners. Some comments, while supportive of the reordering generally, recommended certain changes to the sequence of the sections. One comment requested that the ''Adverse Reactions'' section be moved from its present location following the ''Use in Specific Populations'' section and be placed immediately after the ''Warnings and Precautions'' section. The comment also recommended that the ''Use in Specific Populations'' section be moved from its location following the ''Drug Interactions'' section and be placed immediately after the ''Dosage and Administration'' section. The comment maintained that use in specific populations frequently involves modifications to dose or dosage regimen, so it would be logical to place the section in close proximity to the ''Dosage and Administration'' section.

The agency agrees that it would be advantageous to group together the two major risk information sections—the ''Warnings and Precautions'' and ''Adverse Reactions'' sections. Placing the two sections sequentially consolidates risk information in one location and helps put in context the relative seriousness of the adverse reactions discussed in labeling. Thus, FDA has revised proposed § 201.57(c) to require that the ''Adverse Reactions'' section follow the ''Warnings and Precautions'' section.

The agency does not agree with the recommendation to place the ''Use in Specific Populations'' section immediately after the ''Dosage and Administration'' section. Although some of the information in the ''Use in Specific Populations'' section will have implications for dosing, most of the information in the section will be related to risk. The section is, therefore, more appropriately placed among the other labeling sections related to risk. In addition, the agency believes that all dosing information should be consolidated in a single section. If there are specific recommendations for dosage regimen modifications for use in specific populations, those modifications must be described in the ''Dosage and Administration'' section (see § 201.57(c)(3)).

(Comment 39) One comment requested that the agency require a ''Product Title'' section at the beginning of the FPI. The comment maintained that the title is short and repeating it would be useful to practitioners to avoid confusion.

The option to include a ''Product Title'' section is a vestige of the prescription drug labeling rule finalized in 1979 (44 FR 37434, June 26, 1979). The optional ''Product Title'' section was incorporated in the labeling regulations at that time in response to a comment to the proposed rule that was the basis for the 1979 final rule (44 FR 37440). The comment stated that the proposed labeling requirements did not require identification of the product at the beginning of labeling. Instead, the first required element in the proposed labeling regulations was the ''Description'' section. The comment recommended, and the agency agreed, that certain sections of the ''Description'' section could be pulled out of that section and used as a ''Product Title'' section at the beginning of labeling.

Under this final rule, a ''Product Title'' section is not needed for labeling subject to the requirements of new § 201.57, because under final § 201.57(a)(2), Highlights includes the name of the drug, dosage form, and route of administration and, for controlled substances, the controlled substance symbol. Because this information will appear at the beginning of labeling and is similar to the information required under the ''Product Title'' section, the agency believes it is not necessary or useful to provide the option to include a ''Product Title'' section at the beginning of the FPI. Accordingly, the agency has deleted proposed § 201.56(d)(4) from the requirements for products described in § 201.57(b)(1) (new and more recently approved drug products). This revision does not have any effect on the ''Product Title'' provision in current regulations (§ 201.56(e)(4)), which this final rule retains for products subject to § 201.80.

(Comment 40) One comment stated that, if the agency retains the

requirement for the boxed warning in both Highlights and the FPI, the boxed warning in the FPI should be placed in the ''Warnings and Precautions'' section rather than at the beginning of the FPI.

The agency disagrees. The agency believes that the summary sections in Highlights should appear in the same order as the corresponding sections in the FPI to facilitate access to the more detailed information contained in the corresponding sections in the FPI. The risk information presented in a boxed warning is of such importance that it warrants placement in the most prominent locations.

(Comment 41) Some comments recommended that the ''How Supplied/Storage and Handling'' section be kept at the end of the FPI, rather than moved toward the front of the FPI, as proposed. The comments expressed concern that, because of the variable length of the three labeling sections that precede the ''How Supplied/Storage and Handling'' section, it would not be in a consistent location; therefore, practitioners would have more difficulty locating the section than if it were always at the end of the FPI. One comment stated that pharmacists frequently access this section for information about storage conditions and that it would be more appropriate to place the section just before the ''Patient Counseling Information'' near the end of the labeling, where pharmacists are accustomed to finding it.

The proposed placement of the ''How Supplied/Storage and Handling'' section following the ''Dosage and Administration'' section was based on input from physicians who were surveyed about which information in labeling is most important and frequently referenced. Physicians indicated that their use of the ''Dosage and Administration'' section and the ''How Supplied/Storage and Handling'' section is linked. Physicians commonly refer to the ''Dosage and Administration'' section for dosing information and then to the ''How Supplied/Storage and Handling'' section for available dosage strengths and dosage forms. For this reason, the agency believes that keeping dosing and dosage forms and strengths information together in the labeling is important.

However, the agency recognizes that, under proposed § 201.57(c)(4), the ''How Supplied/Storage and Handling'' section would often have contained lengthy lists of available packaging and product identification information that may distract prescribers from other important information. For this reason, and in view of the comments received, the agency has decided to move this section toward the end of the labeling (§ 201.57(c)(17)). (See comments 55 and 107 for discussion of revisions (i.e., addition of imprinting as an example of an identifying characteristic and deletion of proposed § 201.57(c)(4)(v)).) FDA also has decided to require that information identified by prescribers as frequently referenced (i.e., dosage forms and strengths and some product identification information) be included in a section entitled ''Dosage Forms and Strengths'' (§ 201.57(c)(4)) following the ''Dosage and Administration'' section.

The agency believes that moving the ''How Supplied/Storage and Handling'' section toward the end of labeling will make it easier for pharmacists to locate product identification, packaging, and storage information. Retaining critical prescribing information in the ''Dosage Forms and Strengths'' section will continue to meet the needs of prescribers by keeping available dosage forms and strengths information together with information about dosage and administration. Under this final rule, some product identification information (e.g., shape, color, coating, scoring, and imprinting) may be required to appear in both the ''Dosage Forms and Strengths'' and ''How Supplied/Storage and Handling'' sections. FDA believes that the product identification information should be included in both sections to preserve the integrity and comprehensibility of each section.

(Comment 42) One comment requested that the agency clarify the conditions under which it would be appropriate, when amending existing labeling to the new labeling format, to move certain information from a section in old labeling to a different section in new labeling. For example, the comment asked what criteria would be used to determine whether information on use in specific populations, currently contained in the ''Clinical Pharmacology'' section, should be moved to the new ''Use in Specific Populations'' section.

The agency expects that, in many cases, amending labeling to meet new § 201.57(c) will involve rearranging large segments (sections and subsections) of information in existing labeling without substantially changing the content. In some cases, however, it will be necessary to parse information from several parts of the existing labeling into a new section. When information is to be consolidated into a new section, or when information is required in several places, there may be uncertainty about how the information should be divided into portions for clarity and to avoid redundancy. The agency recognizes the complexity of these issues and, therefore, is making available the new labeling format guidance to assist in determining how to reorganize existing labeling information into the new format (see section IV of this document).

H. Full Prescribing Information—Comments on Specific Provisions

As noted previously, for products described in proposed § 201.56(b)(1) (new and more recently approved prescription drug products), FDA proposed to revise the content and format requirements at then-current § 201.57 (proposed § 201.57(c)). A discussion of the comments pertaining to these provisions and the agency's responses follow.

- *Boxed warning (proposed § 201.57(c)(1))*

FDA proposed to require that a boxed warning in the FPI be preceded by an exclamation point (!) for indexing purposes (proposed § 201.57(c)(1)). The agency specifically requested comment on the different types of icons that could be used to signal the boxed warning and on the costs and benefits of different icon types.

(Comment 43) Several comments stated that an icon is unnecessary because practitioners are familiar with the meaning of a boxed warning and the box itself is sufficient to call attention to the warning. Some comments observed that the exclamation point was not a sufficiently distinct symbol because it could be confused with the numeral 1 and might be particularly difficult to recognize in small font. Some comments expressed concern about using any icon that is not universally understood. One comment recommended that a stop sign be used as it has a universally recognized meaning. Other comments expressed concern about added printing and software costs associated with any icon requirement.

FDA has reconsidered requiring an exclamation point, or any other icon, to identify a boxed warning. FDA agrees that the single black line box around the warning information is understood by practitioners in the United States and is sufficient to draw attention to the warning information. Therefore, the agency is not requiring an exclamation point or any other icon preceding the boxed warning in the FPI. Sections 201.56(d)(1), 201.57(a)(4), and (c)(1) of the final rule have been revised to remove the requirement.

- *Indications and usage (proposed § 201.57(c)(2)(i))*

FDA proposed to require that the ''Indications and Usage'' section of the

FPI (proposed § 201.57(c)(2)(i)) contain the same information as required at then-current § 201.57(c)(1) except that outdated examples of indications were removed.

(Comment 44) One comment recommended that the ''Indications and Usage'' section be retitled ''Food and Drug Administration—Approved Uses.'' The comment stated that the phrase ''indications and usage'' is regulatory jargon that is not meaningful to practitioners or patients.

The agency does not believe it would be worthwhile to change the title of the section in the manner recommended by the comment. The agency does not agree that ''indications and usage'' is jargon and not meaningful to practitioners. FDA believes practitioners are familiar with the section heading and understand that the uses described in this section are those for which FDA has found to be safe and effective.

(Comment 45) One comment stated that the ''Indications and Usage'' section should include approved uses in pregnancy.

The agency agrees, in part. Uses that have been specifically studied for conditions unique to pregnancy and for which a drug has been demonstrated to be safe and effective (e.g., to induce labor) would be appropriate for inclusion in the ''Indications and Usage'' section. Ordinarily, however, special considerations about the use of a drug in pregnancy for indications that do not differ from the general population would be placed in the ''Use in Specific Populations'' section.

• *Indications and usage—scope of information (proposed § 201.57(c)(2)(iv)(A))*

FDA proposed to revise the requirement at then-current § 201.57(c)(3)(i) to state that if evidence is available to support the safety and effectiveness of the drug only in selected subgroups of the larger population with the disease or condition (e.g., patients with mild disease or patients in a special age group) or if evidence to support the indication is based on surrogate endpoints, then the available evidence and the limitations on the usefulness of the drug (or in the case of surrogate endpoints, the limitations of the supporting efficacy data) must be described succinctly in the ''Indications and Usage'' section (proposed § 201.57(c)(2)(iv)(A)). FDA proposed, further, to require reference to the ''Clinical Studies'' section of the FPI (proposed § 201.57(c)(15)) for a detailed discussion of the methodology and results of clinical studies relevant to such limitation(s). FDA also proposed to require that this section of the FPI identify specific tests needed for selection or monitoring of the patients who need the drug and describe, if available, information on the approximate kind, degree, and duration of improvement to be anticipated.

(Comment 46) One comment requested that the ''Indications and Usage'' section specify the type of clinical trial that has been conducted to support each indication (e.g., placebo-controlled, active-controlled).

The agency believes that the ''Clinical Studies'' section is the appropriate section of labeling to discuss the details (e.g., trial design, outcome) of clinical trials, not the ''Indications and Usage'' section. The agency has concluded that greater clarity about the scope of the information to be included in the ''Indications and Usage'' section is warranted and has revised proposed § 201.57(c)(2) accordingly. This revision is consistent with having, as stated in the preamble to the proposed rule, a more focused ''Indications and Usage'' section (65 FR 81082 at 81091).

(Comment 47) FDA received one comment that strongly supported the proposed modification of the ''Indications and Usage'' section to require that limitations in usefulness or in data supporting approval be specified. One comment stated that the requirement should be modified to specifically require discussion of differential drug effects in subpopulations with varying genetic characteristics.

FDA agrees that the ''Indications and Usage'' section must discuss differences in drug effectiveness in subgroups for which there is substantial evidence for such differences. The proposed language was not intended to limit the scope of the requirement to particular subgroups. The provision applies to any identifiable subgroup with a clearly different response to a drug. The agency believes the language in final § 201.57(c)(2)(i)(B) and (c)(2)(i)(D) makes clear that the section must discuss differential drug effects for all types of patient subgroups for which there is substantial evidence establishing differences in effects. If dosage modification is necessary based on genetic characteristics, this must be described in the ''Dosage and Administration'' section. FDA has revised proposed § 201.57(c)(3) accordingly (see § 201.57(c)(3)(i)(H) of final rule).

(Comment 48) One comment requested that FDA make clear when the ''Indications and Usage'' section must include specific tests needed for selection and monitoring of patients who need a drug (e.g., microbe susceptibility testing). The comment stated that it is not practical to recommend specific microbial susceptibility testing when empirical diagnosis is common.

Specific tests for selecting and monitoring patients would be described when they are necessary for safe and effective use. Therefore, the requirement in final § 201.57(c)(2)(i)(C) that the ''Indications and Usage'' section identify specific tests needed for selecting and monitoring patients does not require that the ''Indications and Usage'' section routinely state that microbial susceptibility testing must be done. The requirement addresses situations in which a drug is indicated for a specific therapeutic niche that can be identified by microbe susceptibility testing. For example, the ''Indications and Usage'' section might specify that a drug is indicated to treat penicillin-resistant pneumococci. The description of the drug's activity provides critical prescribing information.

• *Indications and usage—lack of evidence statement (proposed § 201.57(c)(2)(iv)(D))*

FDA proposed to revise then-current § 201.57(c)(3)(iv), which provided that in situations where there is a common belief that a drug may be effective for a certain use or condition or the drug is commonly used for that condition but the preponderance of the evidence shows the drug is ineffective, the ''Indications and Usage'' section must state that the drug is ineffective (proposed § 201.57(c)(2)(iv)(D)). The revision proposed to expand this requirement to situations in which a drug may be effective for a use but the preponderance of the evidence shows that the therapeutic benefits of the product do not generally outweigh its risks. In such situations, under sections 201(n) (21 U.S.C. 321) and 502(a) of the act, the agency can require that the ''Indications and Usage'' section state that there is a lack of evidence that the drug is effective or safe for that use.

(Comment 49) One comment requested that the agency provide examples to clarify what it intends by this new requirement.

Anti-arrhythmia drugs are an example of a category of drugs to which the new requirement in final § 201.57(c)(2)(ii) could apply. They are typically effective in restoring or maintaining normal sinus rhythm for a variety of types of rhythm disturbances, but because of the potential for pro-arrhythmic effects, they are typically indicated for only the more serious clinical situations in which their benefits outweigh their risks. For example, an anti-arrhythmic

drug may be indicated for sustained ventricular arrhythmia, but specifically not indicated for premature ventricular contractions.

• *Dosage and administration (proposed § 201.57(c)(3))*

FDA proposed to require that the ''Dosage and Administration'' section of the FPI (proposed § 201.57(c)(3)) contain the same information as required in then-current § 201.57(j), except that the section must include efficacious or toxic drug or metabolite concentration ranges and therapeutic concentration windows for drug or metabolite(s) where established and when clinically important. FDA proposed to require information on therapeutic drug concentration monitoring (TDM), when clinically necessary. The proposed provision also specified that dosing regimens must not be implied or suggested in other sections of labeling if not included in this section. FDA has retained this provision in the final rule with some editorial revisions (§ 201.57(c)(3)).

(Comment 50) One comment asked the agency to clarify whether the language in proposed § 201.57(c)(3), ''upper limit beyond which safety and effectiveness have not been established,'' is referring to maximum tolerated dose.

The language does not refer to the maximum tolerated dose. The upper limit beyond which safety and effectiveness have not been established would ordinarily refer to: (1) The largest dose demonstrated to be safe and effective in controlled clinical trials, (2) the largest dose evaluated that showed an increase in effectiveness (i.e., where studied larger doses provided no additional benefit), or (3) the largest dose beyond which safety has not been established or an unacceptable risk has been demonstrated.

(Comment 51) One comment requested that the agency make it clear that any dosage adjustments discussed in the ''Drug Interactions'' section should also be presented in the ''Dosage and Administration'' section.

The agency agrees that when there is specific information about how to adjust dosage because of a drug interaction, this information must be included in the ''Dosage and Administration'' section. The ''Dosage and Administration'' section should also refer the reader to the more detailed discussion of the drug interaction in the ''Drug Interactions'' and ''Clinical Pharmacology'' sections. In response to this comment, FDA has modified proposed § 201.57(c)(3) to require that information on dosage adjustments needed because of a drug interaction be included in the ''Dosage and Administration'' section.

(Comment 52) One comment requested that all intravenous dosing regimens in labeling be expressed in rates of milligrams per hour. The comment pointed out that rates are expressed in milligrams per minute and milligrams per hour. The comment maintained that expressing all such rates in milligrams per hour would avoid the need to recalculate rates and thus reduce the likelihood of medication errors.

The agency does not agree that always requiring rates of administration for intravenous medications to be expressed in milligrams per hour would avoid the need to recalculate rates of infusion and thus reduce medication errors. The agency believes that these rates should be expressed per time unit that is most appropriate to the interval over which a medication is to be administered. This approach will eliminate, to the extent possible, the need to recalculate rates and should, therefore, minimize error.

(Comment 53) One comment stated that, with respect to clinically important effectiveness and/or toxic drug and/or metabolite concentration ranges and therapeutic concentration windows in the ''Dosage and Administration'' section, effectiveness information other than information on TDM would more appropriately be placed in the ''Clinical Pharmacology'' section. The comment further stated that, if the concentration range concerned safety, it would more appropriately be included in the ''Warnings and Precautions'' section.

The ''Dosage and Administration'' section must identify efficacious or toxic concentration windows of the drug or its metabolites, if established and clinically significant, and information on TDM, when TDM is necessary. Clinically relevant background information supporting the need for TDM could appear in other sections of labeling as appropriate (e.g., ''Clinical Pharmacology,'' ''Clinical Studies,'' ''Adverse Reactions'').

(Comment 54) Two comments recommended including instructions on the appropriate time of day to take a drug and other dosing conditions (e.g., take with food, take on an empty stomach) in the ''Dosage and Administration'' section of the labeling. One comment requested that the labeling include a section concerning the importance of compliance with the dosage regimen and instructions on what to do about missed doses and noncompliance in general. The comment requested that, in the absence of data to support instructions on what to do about noncompliance, the labeling include a statement indicating that there is no such information.

The agency agrees that information about appropriate time of day to take a medication or other dosing considerations must be included in the ''Dosage and Administration'' section if this information is necessary for safe and effective use (e.g., if a significant amount of a therapeutic effect is lost if the drug is not taken on an empty stomach). Therefore, the agency has revised proposed § 201.57(c)(3) to require that clinically significant dosing information (e.g., clinically significant food effects) be included in the ''Dosage and Administration'' section. Similarly, the agency has revised proposed § 201.57(c)(13)(i)(B) of the ''Clinical Pharmacology'' section to clarify that certain recommendations regarding pharmacodynamic effects included in other sections of labeling, such as the ''Dosage and Administration'' section, must not be repeated in the ''Clinical Pharmacology'' section.

The agency agrees that rigid compliance with the dosage regimen can be critical to safe and effective drug therapy and information about how to manage noncompliance is important for practitioners. Therefore, FDA has revised proposed § 201.57(c)(3) to make clear that important considerations concerning compliance with the dosage regimen must be included.

The agency believes that the labeling should not include a separate section devoted to the importance of compliance with a drug's dosage regimen or information on what to do about missed doses, because this information is most appropriately contained in other sections of the labeling (e.g., ''Dosage and Administration,'' ''Clinical Pharmacology,'' ''Patient Counseling Information''). The agency believes that it would not be useful to include a statement in the labeling indicating that there is no information available about management of noncompliance (e.g., missed doses).

• *How supplied/storage and handling (proposed § 201.57(c)(4))*

FDA proposed to require that the ''How Supplied/Storage and Handling'' section of the FPI (proposed § 201.57(c)(4)) contain the same information as required at then-current § 201.57(k), except that a new provision was added at proposed § 201.57(c)(4)(v). Proposed § 201.57(c)(4)(v) would require a statement specifying the type of container to be used by pharmacists in dispensing the product. Comments pertaining to proposed § 201.57(c)(4)(v) are addressed in section VI.J of this document (''Comments on Revisions to

Container Labels''; see comments 106 through 110). Comment 41 addresses relocation of the ''How Supplied/Storage and Handling'' section to § 201.57(c)(17) and the retention of critical prescribing information in the ''Dosage Forms and Strengths'' section at § 201.57(c)(4). A comment pertaining to the format for and type of information contained in these sections is discussed here.

(Comment 55) One comment recommended including product identity markings in this section. The comment also recommended bulleted or tabular presentation of product identity markings, color, flavor, package sizes, strengths, storage conditions, etc., to make such information more accessible.

FDA agrees with the comment that product identity markings are useful for practitioners and, therefore, now includes imprinting as an example of an identifying characteristic in both the ''Dosage Forms and Strengths'' and the ''How Supplied/Storage and Handling'' sections of the final rule. FDA also agrees that presenting information about product identity markings, color, flavor, package sizes, strengths, storage conditions, and other identifying information in a bulleted or table format will make the information more accessible, particularly where the product has many dosage forms and strengths. However, because the amount and content of information can vary significantly from product to product, FDA is not requiring a specific format.

• *Warnings and precautions (proposed § 201.57(c)(6))*

FDA proposed to revise the content of the ''Warnings'' and ''Precautions'' sections. First, FDA proposed to require that information on drug interactions, information on specific populations (i.e., pregnancy, labor and delivery, nursing mothers, pediatric, and geriatric use information), and information for patients be moved from the ''Precautions'' section to three new sections (described in proposed § 201.57(c)(7), (c)(8), and (c)(17) respectively). Second, FDA proposed to require that the remainder of the information in the ''Precautions'' section, with the information from the ''Warnings'' section, be combined into a new section entitled ''Warnings and Precautions'' (proposed § 201.57(c)(6)).

FDA also proposed to require that the ''Warnings and Precautions'' section include information on contacts for adverse reaction reporting (proposed § 201.57(c)(6)(v)). See comment 30 regarding deletion of proposed § 201.57(c)(6)(v).

Several comments supported reorganizing the ''Warnings and Precautions'' section. The comments agreed with FDA's findings, based on physician surveys and focus testing, that the distinction between warnings and precautions is not meaningful to practitioners who use labeling. The comments stated that the combined section would make the discussion of risk information in labeling less repetitive, less confusing, and more accessible.

(Comment 56) In the proposal, the agency specifically sought comment on whether there should be standardized headings for categories of adverse reactions in the proposed ''Warnings and Precautions'' section and, if there should be, what standardized headings would be appropriate.

Comments uniformly opposed standardized headings to categorize adverse reactions in the ''Warnings and Precautions'' section. Comments expressed concern that standardized headings would not provide sufficient flexibility to accommodate the diversity of risk information that might be appropriate for inclusion in the ''Warnings and Precautions'' section.

FDA agrees that standardized headings should not be required in the ''Warnings and Precautions'' section because a requirement to place risk information under prescribed headings could make the information less clear or more difficult to find.

(Comment 57) One comment requested clarification of the requirement in proposed § 201.57(c)(6)(iii) that the ''Warnings and Precautions'' section identify any laboratory tests that ''may be helpful'' in following a patient's response or identifying possible adverse reactions. The comment maintained that the language ''may be helpful'' is too vague and recommended that the language be changed to specify that only laboratory tests that ''have been shown to be helpful'' be required in the ''Warnings and Precautions'' section.

The agency is concerned that limiting the scope of laboratory testing recommendations identified in labeling to only those tests that have been ''shown to be helpful'' in monitoring patients could exclude sensible and potentially important laboratory testing recommendations. The agency agrees, however, that ''may be helpful'' is a vague standard and, therefore, has amended the provision to require identifying any laboratory tests ''helpful'' in following a patient's response or identifying possible adverse reactions.

(Comment 58) Several comments expressed concern about the proposal to change the criteria for inclusion of adverse reactions in the ''Warnings and Precautions'' section from ''serious'' to ''clinically significant'' adverse reactions. There was concern that the significance of the adverse reactions discussed in the ''Warnings and Precautions'' section would be diluted by the inclusion of less serious adverse reactions in the section, thus undermining the value of the section. Other comments expressed concern that ''clinically significant'' is subject to interpretation and could, in application, result in inconsistency across labeling for different products.

As discussed in the preamble accompanying the proposed rule (65 FR 81082 at 81092), ''serious'' was changed to ''clinically significant'' to expand the scope of the ''Warnings and Precautions'' section to allow for inclusion of adverse reactions that may not meet the regulatory definition of ''serious'' (§ 312.32(a)), but nonetheless have a significant impact on clinical use of the drug. The agency believes that information on both types of adverse reactions is necessary for practitioners to prescribe products safely and effectively and must, therefore, be included in the ''Warnings and Precautions'' section. The agency acknowledges that inclusion of less serious but clinically significant adverse reactions may add to the overall length of the ''Warnings and Precautions'' section of labeling for certain drugs. The agency does not agree, however, that the effect will be to dilute or deemphasize the importance of serious adverse reactions contained in the section. The agency believes that limiting inclusion of nonserious adverse reactions to only those that have significant impact on therapeutic decisionmaking (e.g., may reduce compliance with drug therapy) ensures that the intended scope of the ''Warnings and Precautions'' section is preserved.

(Comment 59) One comment recommended that the agency describe parameters upon which to base decisions about the sequence in which adverse reactions are presented in the ''Warnings and Precautions'' section.

There are multiple factors that could influence the sequence in which adverse reactions should be presented in the ''Warnings and Precautions'' section. The most significant include the relative seriousness of the adverse reaction, the ability to prevent or mitigate the adverse reaction, the likelihood the adverse reaction will occur, and the size of the population affected. In general, the sequence of the adverse reactions should reflect the relative public health significance, and the seriousness of the adverse reaction

should weigh more heavily than the likelihood of occurrence or the size of the affected population. The agency has added clarifying language to this requirement to assist in selecting and organizing information in this section. The agency is also making available guidance on the ''Warnings and Precautions'' section, which provides recommendations on sequencing of adverse reactions (see section IV of this document).

In addition, the final rule (§ 201.57(c)(6)(i)) states that FDA may require labeling to include a specific warning relating to a use that is not provided for under the ''Indications and Usage'' section if the drug is commonly prescribed for a disease or condition and such usage is associated with clinically significant risk or hazard. FDA deleted language from proposed § 201.57(c)(6)(i), (i.e., ''and there is a lack of substantial evidence of effectiveness for that disease or condition'') because the requirement for a warning is based on an assessment of risk. In addition, FDA also clarified that its authority under this provision must be exercised in accordance with sections 201(n) and 502(a) of the act.

• *Drug interactions (proposed § 201.57(c)(7))*

FDA proposed to require a ''Drug Interactions'' section (proposed § 201.57(c)(7)) containing the same information as required by the ''Drug interactions'' subsection of the ''Precautions'' section at then-current § 201.57(f)(4).

(Comment 60) Most comments supported creation of a distinct section for drug interactions. These comments maintained that the new section would improve the safety of drugs for patients on multiple medications. One comment asked FDA to clarify whether discussions of drug interaction pharmacokinetic studies should be repeated in the ''Clinical Pharmacology'' section.

How to divide information on drug interactions between the ''Clinical Pharmacology'' and ''Drug Interactions'' sections is a matter of judgment. Manufacturers must not include a detailed discussion of drug interaction pharmacokinetic studies in both the ''Drug Interactions'' and the ''Clinical Pharmacology'' sections. Ordinarily, clinically significant results and conclusions of such studies must appear in the ''Drug Interactions'' section and clinically significant information on dosing modifications in the ''Dosage and Administration'' section. If additional details about the design or conduct of the studies are relevant to the clinical use of the drug, the information must be included in the ''Clinical Pharmacology'' section. Thus, the agency has revised proposed § 201.57(c)(7)(i) and (c)(13)(i)(D) to provide this clarification (see § 201.57(c)(8)(i) and (c)(13)(i)(C)).

(Comment 61) One comment stated that the labeling example published with the proposed rule included recommended dosage adjustments for drug interactions that are not based on clinical experience and requested clarification about whether the manufacturer must include speculative interactions and dosage adjustments in this section. The comment also asked to what extent sponsors would be required to develop clinical data to support dosage adjustments for drug interactions.

Manufacturers must not speculate in labeling. Information from clinical experience is clearly the most persuasive, but other relevant data, such as pharmacokinetic data, in vitro data, and data from other drug products in the same pharmacologic or chemical class, may reliably predict the likelihood of an interaction with the drug or provide a basis for a dosage adjustment recommendation. Therefore, it would not be appropriate to limit the scope of the drug interactions and dosage adjustment information in labeling to only those interactions or dosage adjustments for which there are clinical data.

(Comment 62) One comment stated that including discussions of dosage adjustments to address drug interactions in both the ''Drug Interactions'' and ''Dosage and Administration'' sections would add unnecessarily to the length of the labeling.

FDA does not agree that discussing dosage adjustments for drug interactions in both the ''Drug Interactions'' section and the ''Dosage and Administration'' section would be unnecessary or repetitive because the purposes of the sections are distinct (see comment 51). The ''Drug Interactions'' section alerts the prescriber to the existence of interactions and provides a place for substantive discussion of the nature of the identified interactions, including practical advice about preventing or limiting interactions. The ''Dosing and Administration'' section provides specific information about how to modify the dose to minimize the risk of drug interactions when such information is available, but does not provide the details that are discussed in the ''Drug Interactions'' section.

(Comment 63) One comment recommended revising the ''Drug Interactions'' section to require the presentation of drug interaction data ranked by order of the strength of the data supporting the existence of an interaction.

FDA believes that relative clinical significance of the drug interaction would ordinarily be the most reasonable basis for determining the order of presentation of drug interactions. Because, for certain products, this section can be lengthy and complex, the agency will not designate a specific order in the regulations.

(Comment 64) One comment recommended that, in the following language from the proposed provision for the ''Drug Interactions'' section, the word ''patients'' be replaced with the word ''humans'': ''Information in this section must be limited to that pertaining to clinical use of the drug in patients.'' The comment maintained that drug interaction studies often involve healthy volunteers, rather than patients, and the language in the regulation should reflect the nature of the study participants.

The agency has revised final § 201.57(c)(8)(i) to clarify the scope of the information to be included in this section and this sentence was deleted.

(Comment 65) One comment requested that the agency clarify the requirement in the proposed ''Drug Interactions'' section to briefly describe the mechanism of interaction for drugs and drug classes that interact with a drug in vivo. The comment maintained that the mechanism is not always understood and requested that the rule specify that the requirement to describe the mechanism applies only if the mechanism is understood.

The agency agrees. Proposed § 201.57(c)(7) (§ 201.57(c)(8)(i) in this final rule) has been revised to state that the mechanism of an interaction must be briefly described, if it is known.

• *Use in specific populations (proposed § 201.57(c)(8))*

FDA proposed to require a new section entitled ''Use in Specific Populations'' (proposed § 201.57(c)(8)) to include the information on specific populations required in the ''Pregnancy,'' ''Labor and delivery,'' ''Nursing mothers,'' ''Pediatric use,'' and ''Geriatric use'' subsections of the ''Precautions'' section at then-current § 201.57(f)(6) through (f)(10). The agency also proposed to revise certain required warning language in the labeling of drugs in pregnancy categories D and X (proposed § 201.57(c)(8)(i)(A)(4) and (c)(8)(i)(A)(5)). The proposal would have replaced the following language from then-current § 201.57(f)(6)(i)(d) and (f)(6)(i)(e): ''If this drug is used during pregnancy, or if the patient becomes

pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.'' The proposed alternative language, which was intended to address the concern that any woman with reproductive potential should be apprised of the risk associated with taking the category D and X drugs during pregnancy, read: ''If this drug is administered to a woman with reproductive potential, the patient should be apprised of the potential hazard to a fetus.''

FDA also proposed some changes in terminology to the ''Nursing mothers'' subsection (proposed § 201.57(c)(8)(iii)). For example, FDA proposed to change the term ''nursing mothers'' to ''lactating women.'' Other proposed changes included making assessments based on ''clinically significant adverse reactions'' rather than ''serious adverse reactions.''

(Comment 66) Several comments supported creation of a section devoted to information about use in specific populations. The comments indicated that placing all the information on specific populations in one labeling section would make the information much easier to locate. However, one comment stated that the revised warning statement for drugs in pregnancy categories D and X no longer makes clear that a pregnant woman receiving the drug should be apprised of the potential hazard to the fetus. The comment expressed concern that the phrase ''women with reproductive potential'' could be interpreted as referring only to women with the potential to become pregnant and not to those who actually are pregnant.

The agency is developing a proposal that would revise the requirements for the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of prescription drug labeling. For this reason, the agency has reconsidered the need to make minor, interim changes to the warning statements for pregnancy categories D and X in this final rule and has decided to retain the language at former § 201.57(f)(6)(i)(d) and (f)(6)(i)(e). This language clearly addresses use of the drug by pregnant women and obviates the need for the changes advocated by the comment.

FDA also decided not to make interim changes to the ''Nursing mothers'' subsection of the labeling and will retain the language at former § 201.57(f)(8) for this subsection. The agency believes that it is best to address all changes to the content of these subsections at one time.

(Comment 67) One comment requested that the agency combine the initiative to revise the requirements for the pregnancy labeling with this rulemaking to revise the requirements of prescription drug labeling generally. The comment maintained that the pregnancy labeling requirements need to be changed expeditiously to require that the labeling address the likelihood of harm to the fetus based on timing of exposure, pharmacokinetic changes in pregnant women, and the relevance of animal data to humans.

The agency does not agree that the two initiatives should be combined. The pregnancy labeling initiative focuses exclusively on revising the content requirements for the pregnancy subsection of labeling to meaningfully describe the risks associated with fetal and maternal exposure to a drug and the clinical implications of those risks. In contrast, this final rule is focused on revising the format and content of labeling to increase its usefulness for health care practitioners.

• *Adverse reactions—definition of adverse reaction (proposed § 201.57(c)(9))*

FDA proposed to revise the definition of ''adverse reaction'' to mean a ''noxious and unintended response to any dose of a product for which there is a reasonable possibility that the product caused the response, i.e., the relationship cannot be ruled out'' (proposed § 201.57(c)(9)).

(Comment 68) Several comments objected to the revised definition of an adverse reaction in proposed § 201.57(c)(9). The comments maintained that this definition would be too restrictive and could result in omission of important information. Comments expressed particular concern that the terms ''noxious'' and ''unintended'' could be applied to exclude important adverse reactions. They also stated that important information could be excluded from the ''Adverse Reactions'' section because manufacturers could narrowly construe whether the drug caused the event. Comments maintained, for example, that an adverse reaction that affects compliance could be considered clinically meaningful and thus merit discussion in the ''Warnings and Precautions'' section, but be excluded from the ''Adverse Reactions'' section because it is not considered noxious or unintended. Some comments requested clarification of elements of the definition—in particular ''noxious,'' ''unintended,'' and ''injurious to health.'' One comment recommended that ''unintended'' be changed to ''unexpected,'' stating that ''unexpected'' may more accurately reflect the intent of the definition. One comment requested that FDA issue guidance to clarify these concepts and conduct an educational campaign to explain the meaning and significance of the new definition. Several comments maintained that the definition of an adverse reaction in then-current § 201.57(g) is a more accurate description of the events that should be included in labeling.

One comment expressed concern that the proposed definition of adverse reaction could result in excluding adverse events that should be included in the labeling because there is a lack of guidance for determining ''reasonable causality'' to identify which adverse reactions to list. The comment said that it is commonly known that prescription drug labeling lists all adverse reactions that occurred in trials, with definite, probable, possible, and remote causality. The comment recommended that significant adverse reactions be listed in Highlights and reinforced in the full prescribing information. The comment also stated that all other events that occurred should still be listed, perhaps last in the comprehensive ''Adverse Reactions'' section, because the loss of a comprehensive listing of all reported events could be detrimental to patient safety.

Some comments stated that the proposed new definition for an adverse reaction was a marked improvement because it would narrow the scope of the ''Adverse Reactions'' section. These comments contended that narrowing the scope of events considered adverse reactions for purposes of the ''Adverse Reactions'' section would help address long-standing practitioner concerns that the section is not very informative because it contains excessively long lists of reactions, many of which are not relevant to clinical use of the drug.

The agency has reconsidered the proposed definition of an adverse reaction, which was intended to conform to the definition of adverse drug reaction for safety reporting in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidance ''E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting'' (60 FR 11284 at 11285, March 1, 1995).

Upon consideration of the comments submitted in response to this proposal, the agency concluded that it should not require use of a new definition of adverse reaction for labeling of new and recently approved products. The agency believes that the language in the definition of adverse reaction at former § 201.57(g) (designated in the final rule

as § 201.57(c)(7)), in particular ''an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence'' is appropriate for labeling, but that it requires clarification, as described in the next paragraph, to minimize including information in labeling that does not help prescribers use the drug safely and effectively (i.e., adverse events that are not related to use of the drug), and that may result in diluting the usefulness of clinically meaningful information. Thus, FDA will, as recommended by several comments, continue to use its existing definition for adverse reaction.

The agency believes, as previously indicated, that the definition of adverse reaction at former § 201.57(g) requires clarification. For this purpose, FDA has revised this definition to make clear that it is specific to prescription drug labeling and does not include all adverse events observed during use of a drug, but only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event. There are many factors to consider in assessing the association between a drug and a reported adverse event and determining whether a reported event is an adverse reaction that should be included in labeling. The agency has included clarifying language in this final rule to assist in selecting and organizing reactions. To further assist manufacturers and reviewers, FDA is making available the ''Adverse Reactions'' section guidance (see section IV of this document).

(Comment 69) One comment expressed concern that inclusion of an adverse reaction in the ''Adverse Reactions'' section under the proposed definition would be tantamount to an admission that the event was caused by a drug for product liability purposes. Another comment stated that having two definitions for adverse reactions (i.e., the definition in proposed § 201.57(c)(9) for new and recently approved drugs and the definition in redesignated § 201.80(g) for older drugs) may have implications for product liability. One comment stated that application of the proposed adverse reactions definition to drugs that have to revise their labeling to implement the new format would require reevaluation of clinical data and a new safety review by the agency. One comment requested the agency clarify whether manufacturers would now have to reclassify or otherwise reassess adverse reactions profiles of products with existing labeling.

The concerns expressed in these comments are based on the proposed adverse reaction definition. Because the agency is not adopting this definition for the purposes of labeling, FDA believes that the concerns expressed in these comments are no longer applicable.

• *Adverse reactions—characterization of adverse reactions (proposed § 201.57(c)(9)(ii))*

FDA proposed to retain the language from then-current § 201.57(g)(2) in proposed § 201.57(c)(9)(ii):

> In this listing, adverse reactions may be categorized by organ system, by severity of the reaction, by frequency, or by toxicological mechanism, or by a combination of these, as appropriate. If frequency information from adequate clinical studies is available, the categories and the adverse reactions within each category must be listed in decreasing order of frequency. An adverse reaction that is significantly more severe than the other reactions listed in a category, however, must be listed before those reactions, regardless of its frequency. If frequency information from adequate clinical studies is not available, the categories and adverse reactions within each category must be listed in decreasing order of severity.* * *

(Comment 70) One comment requested that the agency reconcile apparent inconsistencies between the draft of the ''Adverse Reactions'' section guidance in development and the language in the ''Adverse Reactions'' section of the proposed rule. The comment maintained that the recommended organization in the draft ''Adverse Reactions'' section guidance is not consistent with the organization of the ''Adverse Reactions'' section in the proposed rule. This comment advocated that important points regarding adverse reactions be discussed in both the proposed rule and the ''Adverse Reactions'' section guidance, with extensive detail provided in the guidance document.

Based on this comment and on comments received on the draft ''Adverse Reactions'' section guidance, the agency has revised the regulation on the ''Adverse Reactions'' section at proposed § 201.57(c)(9) (designated in this final rule as § 201.57(c)(7)) to clarify the scope of information for this section of labeling. See comments 71 through 75.

The agency recognizes that the ''Adverse Reactions'' section has evolved over time to a point where it now typically contains several different components (e.g., information from controlled clinical trials, uncontrolled clinical trials, and postmarketing experience). The agency also recognizes that there exists considerable inconsistency in how information in this section is organized and presented across different drug products. To address this problem, the agency recommends, in the ''Adverse Reactions'' section guidance, an organization for the typical components of the ''Adverse Reactions'' section.

Thus, FDA continues, as recommended by the comment, to provide general requirements in regulation and detailed recommendations in guidance. The ''Adverse Reactions'' section guidance provides recommendations for how to select information for inclusion in this section, how to characterize the information, and how to further organize it (see section IV of this document).

(Comment 71) One comment recommended that manufacturers be required to specify in the ''Adverse Reactions'' section what categorization scheme was employed for listing of the adverse reactions.

The agency believes that, in most cases, the basis for the categorization of ''Adverse Reactions'' section will be readily apparent to readers. In rare instances in which the basis for categorization is not apparent, it would be appropriate to identify the categorization scheme employed. The agency has, therefore, determined that it is not necessary to require in regulation that the basis for categorization of adverse reactions be identified for all labeling.

The agency has revised, for the reasons described in the response to comment 70, proposed § 201.57(c)(9)(ii) (designated in this final rule as § 201.57(c)(7)(ii)) to provide clarification for this part of the ''Adverse Reactions'' section. The agency changed the term ''organ system'' to ''body system.'' Although the two terms have been used interchangeably, currently, the term ''body system'' is used most often.

In addition, the agency deleted the option to categorize adverse reactions by toxicological mechanism. After reviewing the 1975 proposed and 1979 final rules, the agency concluded that the term is not clear; therefore, categorization by toxicological mechanism is not an appropriate option for the ''Adverse Reactions'' section.

The agency also made clear that, however categorized, adverse reactions must be listed in order of decreasing frequency.

FDA also removed the requirement that significantly more severe reactions be listed before other reactions regardless of frequency. In most cases, frequency information is paramount, but in other cases, severity information may be more important or a combination of

the two may be the best approach. The categorization scheme selected for the ''Adverse Reactions'' section should be appropriate to the drug's safety database and reflect the relative public health importance of the information.

The agency also clarified that if data are available and important for adverse reactions with significant clinical implications, details about the nature, frequency, and severity of the reaction must be included. This provision makes clear that, in many cases, in addition to lists of adverse reactions, descriptive information is appropriate for inclusion in the ''Adverse Reactions'' section.

(Comment 72) One comment requested that the agency require that adverse reactions identified from postmarketing experience be listed separately from adverse reactions identified from clinical trials.

The agency agrees that adverse reactions identified from domestic and foreign spontaneous reports after a drug is marketed should be listed separately from adverse reactions identified in clinical trials. Adverse reaction data from clinical trials and spontaneous reports communicate different information to practitioners. In clinical trials, subjects are specifically queried about and evaluated for occurrence of adverse events and clinical investigators have requirements for identifying and reporting such events (21 CFR 312.64(b)). Data from clinical trials inform practitioners about the range of adverse reactions that may occur. In addition, because there is typically a comparison to a control group, these data provide an estimate of the incidence and the ability to identify events that, because they are likely to be causally related, represent adverse reactions.

Postmarketing experience with a drug permits observation of suspected adverse reactions in a larger, often more diverse, patient population. This experience may provide an opportunity to identify low frequency reactions and reactions not previously observed because the susceptible population was either excluded from the controlled trials or only included in small numbers. But, to interpret this information accurately, a practitioner must be mindful that postmarketing experience, although more closely reflective of clinical practice, lacks the structure of a clinical trial setting that permits increased precision. For postmarketing reporting, the impetus for reporting, the frequency with which a suspected adverse reaction is reported, and the number of exposures to the drug compared to the number of suspected reactions reported are unknown, making estimation of incidence calculations difficult.

Because these differences significantly affect the interpretation of these complementary sets of data, the agency believes it is important to separate in labeling adverse reactions identified in clinical trials from adverse reactions identified from domestic and foreign spontaneous reports. For precisely these reasons, in the draft ''Adverse Reactions'' section guidance, FDA suggested segregating adverse reactions from spontaneous reports in this section of the labeling. Thus, the agency has revised proposed § 201.57(c)(9)(ii) (§ 201.57(c)(7) in this final rule) by creating a separate listing for each set of adverse reactions within the ''Adverse Reactions'' section.

The agency clarifies that this distinction is between adverse reactions identified in clinical trials and those identified from domestic and foreign spontaneous reports after a drug is marketed. Adverse reactions that are identified in clinical trials conducted after a drug is marketed would be listed under adverse reactions identified from clinical trials.

(Comment 73) One comment requested that, for drugs with multiple doses or indications, the ''Adverse Reactions'' section have a separate presentation of adverse reactions for each dose or indication.

The agency agrees that it is important for the ''Adverse Reactions'' section to call attention to adverse reactions for which there are clinically significant dose-response relationships.

Thus, the agency has revised proposed § 201.57(c)(9) (designated in this final rule as § 201.57(c)(7)) to require manufacturers to include details about the relationship of adverse reactions to drug dose where sufficient data are available and necessary to prescribe the drug safely and effectively. The agency does not believe, however, that it needs to require that separate presentations of adverse reactions always be included for different doses. If there are important differences in adverse reaction rates for different doses, the section can include a single table that directly compares the adverse reactions rates for different doses. Presenting rates for different doses side by side in a table, for example, is an effective way to make a dose-response relationship apparent.

The agency also does not believe that it needs to require a separate presentation of adverse reactions for each indication. Such information could be appropriate for a drug with multiple indications, however, when the adverse reaction profile differs substantially from one indication or population to another, the differences are drug related, and the data have important clinical implications. On the other hand, where differences are relatively minor and not clinically meaningful, separate presentations for multiple indications would not be informative and would detract from more important information.

(Comment 74) One comment requested that the ''Adverse Reactions'' section discuss differences in adverse reaction rates among different demographic subgroups (e.g., men, women, blacks, renally-impaired).

The agency agrees that the ''Adverse Reactions'' section must include information on differences in adverse reactions among demographic subgroups where sufficient data are available and important. Thus, the agency has revised proposed § 201.57(c)(9) (designated in this final rule as § 201.57(c)(7)) to require such information in the ''Adverse Reactions'' section.

• *Adverse reactions—frequency information (proposed § 201.57(c)(9)(ii))*

FDA proposed to retain the language from then-current § 201.57(g)(2) in proposed § 201.57(c)(9)(ii):

> The approximate frequency of each adverse reaction must be expressed in rough estimates or orders of magnitude essentially as follows:
>
> The most frequent adverse reaction(s) to (*name of drug*) is (*are*) (*list reactions*). This (*these*) occur(s) in about (e.g., one-third of patients; one in 30 patients; less than one-tenth of patients). Less frequent adverse reactions are (*list reactions*), which occur in approximately (e.g., one in 100 patients). Other adverse reactions, which occur rarely, in approximately (e.g., one in 1,000 patients), are (*list reactions*).
>
> Percent figures may not ordinarily be used unless they are documented by adequate and well-controlled studies as defined in § 314.126(b) of this chapter (except for biological products), they are shown to reflect general experience, and they do not falsely imply a greater degree of accuracy than actually exists.

For biological products, such figures must be supported by substantial evidence.

(Comment 75) One comment asked the agency to clarify an apparent inconsistency between the proposed rule and the draft ''Adverse Reactions'' section guidance concerning how to characterize the incidence of adverse reactions. The comment pointed out that the proposed rule (which used the same language as in the 1979 final rule) recommended grouping adverse reactions by rough orders of magnitude and encouraged use of the terms ''frequent,'' ''infrequent,'' and ''rare'' in conjunction with orders of magnitude

appropriate for a given drug's safety database. The comment observed that agency guidance discouraged use of these terms when grouping by rough orders of magnitude.

The agency agrees that clarification is needed regarding presentation of incidence information for adverse reactions. The language in the proposed rule is not sufficiently precise to accurately reflect current practices in characterizing the incidence of adverse reactions associated with the use of a drug product. The preamble to the 1975 proposed rule indicates that precise percent figures would be appropriate if there is scientific evidence from well-controlled trials substantiating such figures and when inclusion of percent figures does not falsely imply a greater degree of accuracy than actually exists (40 FR 15392 at 15393, April 7, 1975). The science of clinical trials has progressed so substantially over time that ascertaining such rates is typically part of virtually all drug development programs.

Under current labeling practices, rates of incidence for most adverse reactions identified in controlled clinical trials are expressed as percentages. Current labeling also typically includes percentage rates for comparison groups in clinical trials (e.g., placebo group) where inclusion of such rates would not be misleading. Broader frequency ranges are used only when meaningful percentage rates cannot be determined. Therefore, the agency has revised proposed § 201.57(c)(9) (designated in this final rule as § 201.57(c)(7)) to make it clear that when meaningful adverse reaction rates can be derived (for drug treatment group and comparison groups) and presentation of comparator rates would not be misleading, they must be included in labeling.

The agency also believes it is inappropriate to use nonspecific terms such as ''frequent,'' ''infrequent,'' and ''rare'' when presenting adverse reaction information. The agency believes the science of clinical trials has evolved such that use of those terms in the manner recommended by the 1979 rule is confusing because the terms do not necessarily refer to the same frequency range across different drug products. For example, for product A, ''rare'' might mean an incidence of less than 1/500, but for product B, ''rare'' might mean an incidence of less than 1/1000. Moreover, the terms are imprecise and, even if precise meanings were defined, would reinforce the misconception that frequency is synonymous with seriousness.

The agency believes that identifying the numerical frequency range alone is a clearer way to communicate rough rates of incidence for a group of adverse reactions. Therefore, the agency has revised proposed § 201.57(c)(9) to require that adverse reactions for which meaningful percentage rates cannot be reliably determined (e.g., adverse reactions were observed only in the uncontrolled trial portion of the overall safety database), be grouped within specified frequency ranges as appropriate to the safety database of the drug (e.g., adverse reactions occurring at a rate of less than 1/100, adverse reactions occurring at a rate of less than 1/500) or descriptively identified, if frequency ranges cannot be determined.

(Comment 76) One comment requested clarification on how percentages should be used to characterize the frequency of adverse reactions when percentages are derived from studies that evaluated greater doses than the approved dose. The comment asked whether, in this circumstance, rates of adverse reactions should be omitted from the ''Adverse Reactions'' section.

The agency will determine, during review of an application, whether adverse reaction rates derived from doses greater than recommended doses would be informative for practitioners and not misleading, and thus appropriate for inclusion in labeling. Where there are adverse reaction data from studies using different doses, including doses greater than recommended doses, the agency will evaluate whether pooling or otherwise combining adverse reaction data would more accurately describe the frequency of adverse reactions.

(Comment 77) One comment requested clarification on whether manufacturers are required to identify the total number of patients enrolled in clinical trials in the ''Adverse Reactions'' section.

FDA has revised proposed 201.57(c)(9)(i) (designated in this final rule as 201.57(c)(7)(i)) to clarify that the total number of subjects or patients exposed to the drug, and the extent of exposure, must be identified in the ''Adverse Reactions'' section, so that practitioners can interpret the significance of the data in this section. The ''Adverse Reactions'' section guidance provides recommendations on how to describe the database from which the adverse reaction data in this section are derived (see section IV of this document).

• *Clinical pharmacology (proposed § 201.57(c)(13))*

FDA proposed to require that the ''Clinical Pharmacology'' section (proposed § 201.57(c)(13)) contain three subsections—''Mechanism of action,'' ''Pharmacodynamics,'' and ''Pharmacokinetics.'' Proposed § 201.57(c)(13) also provided for an optional subsection for incorporation of other clinical pharmacology information that does not fit into one of the specified subsections.

(Comment 78) One comment recommended that the ''Clinical Pharmacology'' section be revised to require discussion of a drug's elimination half-life, indicate differences in elimination half-life as a function of age or other subpopulation, and specify the enzyme involved in metabolism (e.g., CYP450).

Under the final rule, elimination half-life of drugs and differences in the elimination half-life as a function of specific populations (including age-related populations) must be reported in the ''Pharmacokinetics'' subsection of the ''Clinical Pharmacology'' section of the labeling (§ 201.57(c)(13)(i)(C)). In addition, if there are clinically significant differences in elimination half-lives among specific populations and those differences require special monitoring or alternate dosing regimens, such information must be included in other sections, such as ''Use in Specific Populations,'' ''Warnings and Precautions,'' and ''Dosage and Administration.'' Information about drug metabolism, including metabolic pathways and the enzyme systems involved, is also required in the ''Pharmacokinetics'' subsection of the ''Clinical Pharmacology'' section.

(Comment 79) One comment requested that FDA clarify the statement in proposed § 201.57(c)(13)(i)(B): ''If pharmacokinetic/pharmacodynamic relationships are not demonstrated or are unknown, the labeling must contain a statement about the lack of information.'' The comment asked that FDA clarify whether the provision is referring to concentration versus response relationships generally.

In response to this comment, the agency has rephrased this provision, as follows: ''Exposure-response relationships (e.g., concentration-response, dose-response) and time course of pharmacodynamic response (including short-term clinical response) must be included if known.'' (See final § 201.57(c)(13)(i)(B).)

(Comment 80) One comment stated that the three new subsections in the ''Clinical Pharmacology'' section will make it easier to find information in the section.

One comment requested that in vitro data supporting the ''Mechanism of action'' subsection in the ''Clinical Pharmacology'' section be permitted to

be included in the subsection because such information is helpful in understanding a drug's physiologic activity and in differentiating a drug from other therapeutic agents.

The agency agrees that the three new subsections should make information easier to find. Because 201.56(d)(2) (proposed 201.56(d)(5)) permits additional nonstandard subsections, FDA deleted ''12.4 other clinical pharmacology information'' (proposed 201.57(c)(13)(i)(D)) from the final rule.

The ''Mechanism of action'' subsection must include information based on in vitro data if the information is essential to a description of the established mechanism of action and the information is clinically relevant. Where in vitro information about mechanism of action is included, the information must not be used as the basis for a clinical comparison (i.e., to differentiate the drug from other therapeutic agents).

(Comment 81) Many comments opposed the proposal (proposed § 201.57(c)(13)(ii) to revise the current ''Clinical Pharmacology'' section to require that in vitro data related to the activity or effectiveness of an anti-infective drug be included in the section only if a waiver is granted under § 201.58 or § 314.126(c) (21 CFR 314.126(c)). While comments conceded that in vitro data have their limitations, the comments maintained that in vitro data for anti-infective agents can be an important component of the total information available for making prescribing decisions in some situations, including: (1) In the absence of susceptibility testing, (2) in treating drug resistant pathogens (e.g., drug-resistant pneumococci), and (3) in treating rare infections. Some comments stated that preventing inclusion of in vitro data that indicate a drug is inactive against a microorganism could result in selection of inappropriate antibiotics and poor clinical outcomes. One comment maintained that some physician organizations effectively endorse use of in vitro data by having guidelines that recommend use of in vitro data as an adjunct to making educated empirical judgments about appropriate anti-infective therapy. Several comments stated that the absence of in vitro data will make it difficult for practitioners to identify appropriate broad spectrum agents when broad coverage is needed. One comment requested that in the event the agency decides to go forward and exclude in vitro data related to effectiveness unless a waiver has been granted, the agency explain in detail the process by which a waiver could be granted.

Several comments expressed concern about the implications of removing in vitro data for devising susceptibility tests for new anti-infective drugs. They stated that these data are relied on by FDA (the Center for Devices and Radiological Health) and by manufacturers of in vitro susceptibility tests in selecting appropriate organisms for which to devise tests. In addition, comments stated the data are used to develop quality control mechanisms for, and to help develop criteria for use in the review and clearance of, susceptibility test devices. Some comments maintained that removal of in vitro data would cause manufacturers not to develop susceptibility tests for organisms for which such tests would be desirable.

One comment supported exclusion of in vitro data from labeling. The comment stated that exclusion of in vitro data that are not adequate to support therapeutic decisionmaking will improve anti-infective therapy and help prevent inappropriate use of antibiotics.

The agency has reconsidered its proposal to exclude from the ''Clinical Pharmacology'' section in vitro data for anti-infectives that are not supported by clinical data. The agency is considering a broad range of issues concerning the development and labeling of anti-infective products, including the types of data that should be obtained to support indications, the way that indications and anti-infectives data should be presented in labeling, and ways to meaningfully address resistance to anti-infective drugs. The agency believes a comprehensive and coordinated approach is needed to address these issues. Thus, FDA is deferring any action on the in vitro data proposals in the ''Clinical Pharmacology'' section of labeling at §§ 201.57(c)(13)(ii) and 201.80(b)(2) until the agency has developed a comprehensive plan. At that time, the agency may repropose changes to the way in which in vitro data are presented in labeling.

(Comment 82) Several comments maintained that the algorithm in the agency's current guidance for industry (''Clinical Development and Labeling of Anti-Infective Drug Products,'' 1992) for determining when it is appropriate to include in labeling in vitro data not supported by clinical data contains adequate safeguards and should continue to be used for determining when to include such data. One comment suggested that labeling users be educated about the criteria for inclusion in labeling of in vitro data not supported by clinical data and how to use such data in making prescribing decisions.

At this time, the agency will continue to rely on the algorithm in its current guidance on clinical development and labeling of anti-infectives for determining when to include in vitro data in the ''Clinical Pharmacology'' section of labeling. As part of the comprehensive evaluation of the way in which anti-infective therapies are currently developed and labeled (see response to comment 81), the agency may reconsider use of the algorithm and make any changes that may be needed. For this reason, the agency will not at this time undertake an educational campaign to educate prescribers about the basis for inclusion of in vitro data in labeling.

(Comment 83) Several comments recommended retaining in vitro data for anti-infective drugs in the ''Clinical Pharmacology'' section and strengthening the current in vitro disclaimer statement that indicates that the clinical significance of the in vitro data is unknown.

Until FDA has developed a comprehensive plan to address the broad range of issues confronting development and labeling of anti-infective products, the agency will defer any decisions about the content of the disclaimer that accompanies in vitro data indicating that the clinical significance of the data is unknown.

(Comment 84) One comment requested that the agency clarify the scope of the proposed exclusion of in vitro data to make clear that it does not encompass in vitro data with clinical substantiation. The comment maintained that in vitro susceptibility data from large scale clinical trials would provide some basis for making an informed decision about possible effectiveness in the absence of susceptibility testing (e.g., while awaiting such testing) and that this information is especially important for antiviral drugs.

In vitro data that are supported by clinical data have certain problems in common with in vitro data not supported by clinical data (e.g., antimicrobial susceptibilities are constantly changing and vary by location). In vitro and animal data not supported by clinical data were the focus of the agency's proposal to exclude in vitro and animal data from the ''Clinical Pharmacology'' section (§ 201.57(c)(13)(ii)). As discussed previously, the agency has reconsidered its proposal to exclude such data from

labeling and will defer any action until it has developed a comprehensive plan.

(Comment 85) Several comments recommended that in vitro susceptibility data for anti-infectives be retained in labeling and be placed in a new labeling section entitled ''Clinical Microbiology.''

The agency believes that a labeling section devoted specifically to clinical microbiology data is not needed at this time. As a result of its ongoing comprehensive evaluation of anti-infectives drug development and labeling practices, the agency may reconsider the need for a separate section on clinical microbiology.

• *Nonclinical toxicology (proposed § 201.57(c)(14))*

FDA proposed to require a new section in the FPI entitled ''Nonclinical Toxicology'' (proposed § 201.57(c)(14)) to contain information from then-current § 201.57(f)(5) (the ''Carcinogenesis, mutagenesis, impairment of fertility'' subsection) and then-current § 201.57(l) (the ''Animal Pharmacology and/or Animal Toxicology'' section).

(Comment 86) One comment requested that FDA provide guidance clarifying when it would be appropriate to omit the ''Nonclinical Toxicology'' section.

Although the final rule provides that any section of labeling would be omitted if it is clearly inapplicable (see § 201.56(d)(4)), it is unlikely that the ''Nonclinical Toxicology'' section, in its entirety, would ever be inapplicable. Animal data are often the only practical and ethical means to understand a product's potential for certain kinds of toxicity (e.g., carcinogenicity, mutagenicity, reproductive and developmental toxicity). In addition, even if carcinogenicity data are not available, the labeling must state that these studies were not done (§ 201.57(c)(14)(i)). The final rule provides, however, that the ''Animal toxicology and/or pharmacology'' subsection must include certain data that do not appear elsewhere in the labeling. This means that this subsection would be omitted if all the required information appears in one or more of the other labeling sections (§ 201.57(c)(14)(ii)).

• *Clinical studies (proposed § 201.57(c)(15))*

FDA proposed to require a section in the FPI entitled ''Clinical Studies'' (proposed § 201.57(c)(15)). The section would be required to contain a discussion of clinical studies that are important to a prescriber's understanding of the basis for approval of the drug product, including the extent and limitation of the product's benefits, how the drug was used in clinical trials, who was studied, and critical parameters that were monitored.

(Comment 87) One comment requested that the agency clarify the extent to which secondary endpoint data, quality of life data, and pharmacoeconomic data would be permitted in the ''Clinical Studies'' section.

The ''Clinical Studies'' section must describe those studies that facilitate an understanding of how to use a drug safely and effectively. Generally, this means those studies that were essential to establishing the drug's effectiveness for the purpose of obtaining marketing approval.

If studies were appropriately designed to evaluate secondary endpoints, it may be appropriate to include a discussion of these secondary endpoints in the section.

The agency would evaluate the appropriateness of including quality of life and pharmacoeconomic data according to the same standard. The data could be appropriate for inclusion in the section if all of the following apply: (1) The data are from adequate and well-controlled trials that incorporated quality of life or pharmacoeconomic endpoints in their design and carried out appropriate analyses, (2) for pharmacoeconomic studies, the findings are reasonably generalizable to most clinical environments, not just the ones studied, and (3) the information would be important to a practitioner's understanding of how to use the drug in a clinical setting. The ''Clinical Studies'' section guidance contains FDA's recommendations on what studies are appropriate for inclusion in the ''Clinical Studies'' section (see section IV of this document).

(Comment 88) Some comments requested that the agency reconsider its proposal to bar, in the ''Clinical Studies'' section, inclusion of data concerning indications and doses that are not consistent with the approved indications and dosing regimens. Comments maintained that such information can be important to a practitioner's understanding of a product's clinical and safety profile, as well as to an understanding of the approved indication. Some comments stated that all studies that are scientifically sound and provide medically relevant information should be included in the ''Clinical Studies'' section. One comment stated that practitioners understand that data presented in the ''Clinical Studies'' section, as opposed to the ''Indications and Usage'' or ''Dosage and Administration'' sections, are intended for informational purposes only (i.e., not to suggest claims).

One comment asked that the agency make clear that the limitation on inclusion of information in labeling about unapproved doses and regimens would not preclude discussion of a dose ranging study that supports approval and includes dosage regimens that were not approved for use.

One comment agreed with the proposed revision to exclude from the ''Clinical Studies'' section data and information concerning indications and dosing that are not consistent with the information in the ''Indications and Usage'' and ''Dosage and Administration'' sections. The comment maintained that inconsistent information about indications and dosing creates confusion and contributes to uncertainty and distrust of information in the labeling.

Some comments stated that if the agency has concerns about the implications of labeling on product promotion, these can be addressed through its existing legal authority and should be addressed as a separate issue.

The agency requires that claims in any section of labeling, expressed or implied, be supported by substantial evidence (§ 201.56(a)(3)). This requirement would not preclude discussing in labeling an adequate and well-controlled clinical study, including a dose ranging study that has treatment arms with dosing regimens that are not recommended, if the data for the use of such regimens are important to a practitioner's understanding of how to use the drug safely and effectively. For instance, it might be important to include such data if the data indicate that a particular dosage regimen is not effective, is minimally active, provides no benefit compared to lower doses, or is associated with an unacceptable level of toxicity. If data that include dosage regimens other than recommended regimens are discussed in the ''Clinical Studies'' section, the data must be accompanied by a statement appropriately qualifying the data and indicating that those dosage regimens have not been found safe and effective by FDA, if such a statement is necessary for the labeling to be truthful and not misleading.

The agency agrees that advertising and promotional labeling regulations address product promotion issues and that this final rule is not an appropriate context for discussion of these issues.

• *References (proposed § 201.57(c)(16))*

FDA proposed to permit references to be included in labeling in place of a detailed discussion of a subject that is of limited interest, but nonetheless important (proposed § 201.57(c)(16)). The proposed provision stated that the reference must be based on an adequate and well-controlled clinical investigation under § 314.126(b) or, for a biological product, upon substantial evidence of effectiveness.

(Comment 89) One comment maintained that requiring that all information contained in the ''References'' section be based on adequate and well-controlled trials will result in omission of important references for many anti-infective products, including references for standardized test methodology in in vitro studies.

The agency believes that inclusion of a reference to clinical data will be unusual. Any clinical data that are important to a prescriber's understanding of the safe and effective use of the drug must be summarized in the ''Clinical Studies'' section, rather than referenced in the ''References'' section. The ''References'' section may cite an authoritative scientific body, standardized methodology, scale, technique, or similar material important to prescribing decisions that are mentioned in another section of labeling, but cannot readily be summarized. The agency has revised proposed §§ 201.57(c)(16) and 201.80(l) to make this clear and to delete the requirement that limits the ''References'' section to references to adequate and well-controlled clinical studies.

(Comment 90) One comment noted that, even though the conditions for including references in the proposed rule are essentially the same as in the requirements for old labeling, there are substantial differences in the way these conditions are applied across new drug reviewing divisions.

As discussed in the response to the previous comment, in this final rule, the agency has clarified the conditions under which it is appropriate to include a reference in prescription drug labeling. The agency appreciates the comment's concern about inconsistent application of the criteria for inclusion of references across different new drug review divisions. As part of its internal efforts to implement this final rule and related labeling initiatives, the agency intends to make considerable efforts to ensure consistent application of the requirements.

• *Patient counseling information (proposed § 201.57(c)(17))*

FDA proposed that the ''Information for patients'' subsection of the ''Precautions'' section (required under then-current § 201.57(f)(2)) be made a separate section entitled ''Patient Counseling Information'' (proposed § 201.57(c)(17)). The section would be placed at the end of the FPI.

The agency also proposed to require in proposed § 201.57(c)(17) that any approved printed patient information or Medication Guide be referenced in the ''Patient Counseling Information'' section and that the full text of the approved printed patient information or Medication Guide be reprinted immediately following the section.

(Comment 91) One comment supported the proposal to put information for patients in its own section and change the name from ''Information for patients'' to ''Patient Counseling Information.'' The comment stated that the name change is important because it emphasizes the need to counsel patients on their medications and not just provide printed materials.

As described in the proposed rule, FDA determined to change the heading of the information required under then-current § 201.57(f)(2) from ''Information for patients'' to ''Patient Counseling Information'' to clarify that the information under this section is not intended to be distributed to patients, but is intended to help practitioners communicate important drug information to patients.

(Comment 92) Some comments requested that the agency clarify the meaning of ''any approved printed patient information.'' One comment also asked that the agency clarify ''Medication Guide.''

FDA has revised the terminology in the final rule to clarify the meaning of ''any approved printed patient information'' and ''Medication Guide.'' The term ''FDA-approved patient labeling'' refers to any labeling that has been reviewed and approved by the agency that provides information for patients and is for distribution to patients who are prescribed a drug. This term includes approved printed patient information specifically required by regulation (e.g., for oral contraceptives (21 CFR 310.501) and estrogens (21 CFR 310.515)) and patient labeling that is submitted voluntarily to FDA by manufacturers and approved by the agency. FDA-approved patient labeling may have different functions reflected in the type of information conveyed to patients. For example, some FDA-approved patient labeling contains risk information, and some contains only detailed instructions about how to administer a drug product.

Medication Guides are a specific category of FDA-approved patient labeling. Under part 208 (21 CFR part 208), FDA can require a Medication Guide for a prescription drug product that FDA determines poses a serious and significant public health concern requiring distribution of FDA-approved patient information (§ 208.1(a)). Medication Guides are subject to specific content and format requirements (§ 208.20).

(Comment 93) Some comments supported the proposed requirement to reprint FDA-approved patient labeling at the end of the ''Patient Counseling Information'' section so that this information is readily accessible for healthcare practitioners. Other comments requested that the agency reconsider the proposal to require that FDA-approved patient labeling be printed at the end of the FPI. Some comments asked whether attaching prescription drug labeling without FDA-approved patient labeling to trade packaging and attaching the FDA-approved patient labeling separately would satisfy the requirement. Some comments expressed concern that prescription drug labeling with the FDA-approved patient labeling reprinted at the end may make it more difficult for patients to find and read the patient information. One comment stated that patient information typically uses larger fonts and may use color and illustrations, making it difficult and costly to reprint in the prescription drug labeling. Some comments also expressed concern that inclusion of FDA-approved patient labeling would make the labeling too long and impose additional costs because it could necessitate redesign and enlarging of trade packaging. One comment asked whether it would be sufficient to provide only a reference to FDA-approved patient labeling in the ''Patient Counseling Information'' section instead of reprinting the information in the section.

FDA believes that it is crucial that prescribers have ready access to FDA-approved patient labeling so that they are aware that the information exists, can familiarize themselves with the content of that information, and can explain the information to their patients. The agency believes this objective can best be accomplished by requiring that this information be reprinted at the end of prescription drug labeling. Thus, it would be insufficient to provide only a reference to FDA-approved patient labeling in the ''Patient Counseling Information'' section.

However, the agency is persuaded that reprinting the FDA-approved patient labeling at the end of the

labeling is not the only approach that would successfully address the need to familiarize prescribers with this information. Therefore, the agency has revised the requirements at §§ 201.57(c)(18) and 201.80(f)(2) to require that FDA-approved patient labeling either accompany the prescription drug labeling or be reprinted at the end of such labeling (i.e., immediately following the ''Patient Counseling Information'' section of the FPI for products subject to § 201.57(c)(18) or after the last section of labeling for products subject to § 201.80(f)(2)).

The agency acknowledges that, in cases for which FDA-approved patient labeling is included with prescription drug labeling, additional costs will be incurred by the manufacturer. To help minimize the added cost, FDA has revised proposed § 201.57(c)(18) to specify that the same type size requirements that apply to prescription drug labeling (§ 201.57(d)(6)) also apply to FDA-approved patient labeling that is printed at the end of the labeling or accompanies labeling, unless a Medication Guide is to be distributed to patients in compliance with § 208.24 (see table 7 of this document). In most cases, this will be a minimum type size of 8 points. For trade labeling, this will be a minimum type size of 6 points (see response to comment 102 for discussion of 6-point minimum type size for trade labeling for products subject to § 201.57). For Medication Guides to be distributed to patients, the type size requirements set forth at § 208.20 apply. With regard to the labeling for products subject to § 201.80, the agency clarifies at § 201.80(f)(2) that the font size requirement for Medication Guides in § 208.20 does not apply to a Medication Guide that is printed in prescription drug labeling unless it is intended to comply with § 208.24 (i.e., the requirement to distribute Medication Guides to patients). Thus, for these products, there is no minimum font size requirement for FDA-approved patient labeling that is included with labeling but not for distribution to patients (see table 7).

TABLE 7.—TYPE SIZE REQUIREMENTS FOR LABELING AND FDA-APPROVED PATIENT LABELING INCLUDED WITH LABELING

Labeling	Type Size Requirements for Labeling	FDA-Approved Patient Labeling Included with Labeling	Type Size Requirements for FDA-Approved Patient Labeling
New Format (§ 201.57)			
Trade Labeling (i.e., labeling on or within the package from which the drug is to be dispensed)	Minimum 6-point type	FDA-approved patient labeling that is not for distribution to patients	Minimum 6-point type
		Any FDA-approved patient labeling except a Medication Guide that is for distribution to patients	Minimum 6-point type
		Medication Guide that is for distribution to patients	Minimum 10-point type
Other Labeling (e.g., labeling accompanying promotional materials)	Minimum 8-point type	FDA-approved patient labeling that is not for distribution to patients	Minimum 8-point type
		Any FDA-approved patient labeling except a Medication Guide that is for distribution to patients	Minimum 8-point type
		Medication Guide that is for distribution to patients	Minimum 10-point type
Old Format (§ 201.80)			
Trade Labeling and Other Labeling	No minimum requirement	FDA-approved patient labeling that is not for distribution to patients	No minimum requirement
		Any FDA-approved patient labeling except a Medication Guide that is for distribution to patients	No minimum requirement
		Medication Guide that is for distribution to patients	Minimum 10-point type

(Comment 94) One comment asked whether the agency meant for the prescription drug labeling with the FDA-approved patient labeling reprinted at the end to replace the stand-alone FDA-approved patient labeling required to be distributed to patients. The comment asked if the combined document would satisfy the requirement to distribute the FDA-approved patient labeling to patients who have been prescribed the drug. Other comments asked whether FDA-approved patient labeling attached to prescription drug labeling in a way that would facilitate it being torn off (e.g., along a perforation line) would satisfy these requirements. One comment noted that if the FDA-approved patient labeling is appended to the prescription drug labeling as a perforated attachment, it might be more difficult for the patient to receive information at the pharmacy because the pharmacist would have to separate the patient information from the prescription drug labeling.

The agency does not mean for prescription drug labeling with the FDA-approved patient labeling reprinted at the end to replace the stand-alone FDA-approved patient labeling required to be distributed to patients. FDA has long stressed the importance of providing such information to consumers.

However, if the FDA-approved patient labeling is appended to the prescription drug labeling (e.g., as a perforated attachment that can be torn off and given to patients) and is formatted as

required for distribution to patients (§ 208.20), it would meet the requirement to provide information to patients. For example, for a product subject to § 201.57 with a Medication Guide, trade labeling for the product would be required to be in at least 6-point type (see comment 102 of this document), while the Medication Guide, if reprinted as a perforated attachment to the labeling for distribution to patients, would be required to be in a minimum 10-point type (see table 7). For products subject to § 201.80 with a Medication Guide, there is no minimum font size requirement for the labeling, while the Medication Guide, if reprinted as a perforated attachment to the labeling for distribution to patients, would be required to be in a minimum 10-point type (see table 7). The agency does not agree that distributing prescription drug labeling with the FDA-approved patient labeling appended as a perforated attachment will make it more difficult for the patient to receive information at the pharmacy because the pharmacists would have to detach the patient information.

(Comment 95) One comment sought clarification of what information should be included in the ''Patient Counseling Information'' section. The comment expressed concern about how the information in this section is to be communicated to patients.

The ''Patient Counseling Information'' section contains information that the practitioner may decide to convey to the patient at the time of prescribing for the drug to be used safely and effectively (e.g., warnings about driving if the product causes drowsiness, or the concomitant use of other substances that may have harmful additive effects). The information in this section will vary depending on the safety and efficacy characteristics of the product and how it is taken.

FDA believes that requiring a separate ''Patient Counseling Information'' section and a reminder message in Highlights directing practitioners to this section will make patient counseling information in labeling more accessible to health care practitioners. These requirements will increase the accessibility of the section and should reinforce the need for practitioners to counsel their patients, thereby fostering communication between practitioners and patients about prescribed drugs.

(Comment 96) One comment asked whether including the FDA-approved patient labeling in the ''Patient Counseling Information'' section would be sufficient to meet the content requirements for the section.

Including only the FDA-approved patient labeling in the ''Patient Counseling Information'' section is not sufficient to meet the requirements of this section. This section, like the other sections of prescription drug labeling, is specifically written for health care practitioners. Its purpose is to inform practitioners about what information is important to convey to the patient at the time of prescribing for the drug to be used safely and effectively. FDA-approved patient labeling, in contrast, is specifically written for a lay audience and is intended to be read by patients.

The agency emphasizes how important it is that prescribers be informed about what they should communicate to their patients. On the basis of a series of national telephone surveys conducted by FDA to assess how patients receive information about their prescription medicines, the agency determined that the prescribing physician is the primary source of drug information for patients (Ref. 5). The most recent survey, conducted in 1998, showed that more patients received verbal prescription medicine information at their physician's office (69 percent) than at the pharmacy (43 percent) (Ref. 5). In addition, although 74 percent of patients reported receiving written information at the pharmacy, of those who received written information at the pharmacy, 85 percent received instruction sheets and 83 percent received stickers on the medicine container, but only 38 percent received brochures about the medicine. These results indicate that most consumers who receive product information, other than instructions for use or the sticker information, receive it orally from their physicians during an office visit.

(Comment 97) One comment asked whether products with existing labeling that will be required to convert to the new labeling format will be required to have a ''Patient Counseling Information'' section if the product's existing labeling does not contain an ''Information for patients'' subsection in its ''Precautions'' section.

If a product that does not have an ''Information for patients'' subsection becomes subject to the new content and format requirements at § 201.57, the product's manufacturer would be required to develop a ''Patient Counseling Information'' section for the product's prescription drug labeling unless a ''Patient Counseling Information'' section would be clearly inapplicable (see § 201.56(d)(4)) and thus not required. The agency anticipates that few products would qualify for such an exception. The agency believes that the vast majority of products that will be required to have a ''Patient Counseling Information'' section will already have an ''Information for patients'' subsection in their existing labeling on which to base the ''Patient Counseling Information'' section. Thus, this new requirement is anticipated to impose minimal burdens on manufacturers.

I. Comments on the Format Requirements (Proposed § 201.57(d))

FDA proposed new format requirements for prescription drug labeling (proposed § 201.57(d)). The proposed provisions set forth minimum standards and requirements for many of the key graphic elements of labeling (e.g., type size, letter and line spacing, and contrast).

(Comment 98) Some comments recommended implementation of the proposed changes solely or primarily as part of the electronic labeling initiative. Some comments requested that the new format requirements not be implemented for prescription drug labeling required to be distributed with a drug in trade packaging. They pointed out that using an electronic format would permit use of larger print size, hypertext linking to all sections of labeling, links to newly revised sections of labeling, key word searches, and links to patient information without affecting the size of trade packaging. The comments maintained that larger trade packaging will be required to accommodate larger labeling that will result from the new format requirements.

The agency agrees that use of the required format in conjunction with an electronic medium may have benefits over paper labeling. As discussed in section V of this document, the agency believes that, in the future, the Internet and other electronic sources for labeling will most likely be the primary means for delivering drug information to practitioners. At the present time, however, some practitioners may not have the requisite computer equipment or skills to access prescription drug labeling in an electronic format. The agency anticipates that it will be several years before the phase-out of paper labeling as the major source of prescribing information can begin. Therefore, the agency believes that it is important to establish minimum format requirements for paper labeling.

(Comment 99) One comment recommended the use of more blank space among sections of Highlights. The comment expressed concern that, because Highlights contains a significant amount of information in a constrained space and uses a variety of

formatting techniques, the overall effect would be confusing. One comment stated that the placement of the ''Patient Counseling Information Statement'' above the ''Highlights Limitation Statement'' in Highlights is not ideal because it appears that the ''Patient Counseling Information Statement'' is the title of the limitation statement. The comment also requested that the FPI be required to be in a two-column format because such a format enables users to stay better aware of the overall information structure, as well as read individual sections more easily.

The agency believes that use of more blank space in Highlights would not be feasible because additional blank space would increase the length of Highlights and of labeling generally. The one-half page length limitation for Highlights is based on the strong preferences of physicians surveyed in developing the prototype for the new labeling format in the proposed rule. Physicians reacted negatively to prototype Highlights that were one or one and one-half pages long. They indicated that the utility of Highlights decreased significantly as its length increased. In addition, there was significant concern from manufacturers about the costs associated with adding to the length of labeling.

The agency also believes that the formatting techniques used in Highlights help make the information accessible, notwithstanding the density of the section. Therefore, the agency does not believe that it is necessary to include more blank space in Highlights.

The agency agrees that the formatting and placement of the ''Patient Counseling Information Statement'' and the ''Highlights Limitation Statement'' in Highlights could be improved to better communicate the discrete information provided by each statement. For this reason, and in response to comments recommending greater prominence for the ''Highlights Limitation Statement,'' the agency moved this statement to appear at the beginning of Highlights (see comment 35). The agency also removed the requirement at proposed § 201.57(d)(3) that the ''Patient Counseling Information Statement'' be presented in the center of a horizontal line, so that it does not appear to be a section title.

The agency agrees that a two-column format is effective, but believes other formats may be equally effective in conveying prescription drug information and, therefore, is not requiring a two-column format for the FPI.

• *Bolding (Proposed § 201.57(d)(5))*

In the proposal, the agency specifically sought comment on whether the requirement in proposed § 201.57(d)(5) to bold the information required by proposed § 201.57(a)(1) through (a)(4), (a)(11), and (a)(15) (i.e., the following information in Highlights: Drug names, dosage form, route of administration, and controlled substance symbol; the inverted black triangle symbol; the prescription drug symbol; boxed warnings or contraindications; adverse reaction reporting contacts; and Highlights limitation statement) would ensure the visual prominence of the bolded information or whether different highlighting methods would be more effective.

(Comment 100) Most comments expressed satisfaction that bolding was adequate to ensure the visual prominence of the specified information. Some comments stated that capitalization, italics, and underlining, also effective methods of ensuring prominence and flexibility, should be maintained. Some comments expressed concern that possible alternative methods of ensuring visual prominence (e.g., color printing) would add unnecessary costs. One comment requested that, if color is required, specific Pantone colors be assigned to specific types of information to ensure consistency in all product labeling.

The agency recognizes that use of different methods to ensure prominence may decrease their impact and significance. Therefore, FDA concludes that bolding alone is adequate to achieve visual prominence for the specified information in Highlights. The agency also agrees that color printing would add cost and impose an additional burden on manufacturers that would not be offset by meaningful improvement in visual prominence. Therefore, § 201.57(d)(5) requires the following Highlights information to be in bold type: Highlights limitation statement; drug names, dosage form, route of administration, and controlled substance symbol; the initial U.S. approval statement and year of this approval; boxed warnings; adverse reaction reporting contacts; and the patient counseling information statement.

(Comment 101) One comment requested that the agency revise the format of Contents to make it easier to read and use. The comment stated that the information in Contents is not as accessible as it could be because it uses straight columns, which make it hard to distinguish the major labeling sections (e.g., ''Use in Specific Populations'') from subsections (e.g., ''Pregnancy''). The comment recommended use of contrasting font types and sizes for the section titles and subheadings in each section, underlining section titles, indenting subheadings under each section title, and providing more blank space between each section. Another comment also recommended indenting the subheadings under the major sections to more readily distinguish between the major sections and the subheadings within the sections.

The agency agrees that all the recommended revisions to the format of Contents could make the information easier to read and use. Because of cost and space constraints, however, the agency believes that it is impractical to implement all of the recommended changes. FDA has revised the format requirements at proposed § 201.57(d) to now require that the subheadings under each section heading in Contents be indented (§ 201.57(d)(10). In addition, the final rule now requires that only the headings in Contents be bolded, not the subheadings (§ 201.57(d)(10)). The agency believes these changes make the Contents easier to read and use without increasing its length or attendant costs.

(Comment 102) In the proposal, the agency specifically sought comment on whether the proposed requirement (proposed § 201.57(d)(6)) for a minimum type size of 8 points for all typeface information in labeling is sufficient or whether a minimum type size of 10 points would be more appropriate. Currently, prescribing information is usually printed in 6- or 7-point type.

One manufacturer stated that 6-point type was generally adequate for prescribing information, and another manufacturer stated that it typically uses 4- to 6-point type. Some manufacturers were concerned that a minimum 8-point type would increase the length of labeling to such an extent that trade packaging would have to increase in size to accommodate the longer labeling and the increase in size would impose substantial costs. One comment recommended that prescribing information that accompanies trade packaging not be subject to the 8-point type minimum, while prescribing information that is distributed in other contexts, where it is more likely to be referenced by the prescriber (e.g., prescribing information in electronic format, prescribing information accompanying promotional materials and product samples), be required to be in at least 8-point type. Some manufacturers stated that 8-point type was adequate for prescribing information included in trade packaging, but that a minimum 10-point type would increase the length of labeling to such an extent that trade packaging would have to increase in

size to accommodate the larger prescribing information.

Some consumers and health care advocacy organizations requested that the agency reconsider whether the increase to an 8-point minimum type size was sufficient to achieve the agency's goal of improving the readability of the prescribing information. They stated that, to improve readability, labeling should be printed in a type size larger than 8 points and with more white space. They urged the agency to test prototypes to compare the relative readability of 8-point versus 10-point type. Some comments advocated that the minimum type size should be at least 10 points, and preferably 12 points, for all patient information.

In the preamble accompanying the proposed rule, FDA summarized studies that demonstrated the importance of type size in evaluating readability of written information and its effect on visibility and reading speed (see 65 FR 81082 at 81096 and Refs. 6 through 9). Type size combined with other graphical elements (e.g., letter and line spacing, contrast, print and background color, and type style) also affect readability (Ref. 10).

The agency carefully considered the literature, the comments submitted in response to the font size proposal, and the estimated costs of using various font sizes for labeling, and has determined that permitting different font sizes for trade labeling (i.e., labeling on or within the package from which the drug is to be dispensed) and labeling disseminated in other settings (e.g., labeling that accompanies prescription drug promotional materials) best achieves the agency's objective of ensuring an acceptable base level of readability for prescription drug labeling while, at the same time, minimizing costs to manufacturers. Even though a larger font size may improve readability, the agency believes that an 8-point minimum type size, combined with other required graphical elements (e.g., bold type, bullets, demarcation lines), is adequate for prescription drug labeling disseminated in settings where it is likely to be referred to by prescribers (e.g., labeling that accompanies drug promotional materials). The agency believes that the 8-point minimum type size reasonably balances the agency's objective of improving the readability of labeling with the costs associated with the resultant increase in the length of the labeling.

The agency also agrees with the comments requesting that there be an exception for trade labeling. FDA believes that a minimum 6-point type size requirement is satisfactory for such labeling. FDA's telephone survey of office-based physicians showed that the prescribing information in trade labeling is referred to by physicians substantially less frequently than other sources of prescribing information (Ref. 11, p. 30). Because manufacturers could incur substantial costs in converting trade labeling to 8-point type and the public health benefits of such conversion may not justify these costs, the agency believes it is reasonable to allow a 6-point minimum type size for trade labeling (see comment 124). Thus, proposed § 201.57(d)(6) was revised to permit a 6-point minimum type size for trade labeling.

The agency disagrees with the comment that recommended use of type sizes smaller than 6 points because such labeling would not be sufficiently readable. The final rule on OTC drug labeling requirements summarized research on smaller font sizes, noting that a significant portion of the adult population is not able to read OTC drug product labeling with 4.5-point type size (see 64 FR 13254 at 13264 and 13265, March 17, 1999).

The agency acknowledges those comments that urge even larger minimum type sizes to further increase readability. The agency agrees that, absent any cost or space constraints, a 10- or 12-point minimum type size would be preferable to 8-point. However, the agency believes that the 8-point minimum type size requirement for all labeling except trade labeling and the variety of formatting techniques incorporated into the new labeling format will substantially improve the readability of labeling without imposing unreasonable costs on manufacturers. Moreover, this final rule establishes minimum type sizes, but does not prevent manufacturers from printing labeling in larger type sizes.

(Comment 103) One comment requested that the agency require Roman typeface in labeling for optimal legibility. The comment stated that Roman is a major improvement over currently used sans serif, and that sans serif is only appropriate in applications where appearance is more important than legibility (e.g., advertising).

The agency does not agree that FDA should require a specific typeface for all prescription drug labeling. The agency believes that any typeface that is clear and legible should be acceptable in labeling.

(Comment 104) In the proposal, the agency specifically sought comment on whether the requirement in proposed § 201.57(d)(8) for a one-half page limit on Highlights is adequate or whether there are alternatives that would be more appropriate and under what circumstances such alternatives should be considered.

Some comments stated that the one-half page length restriction should be required for all products (i.e., there are no circumstances in which the limitation should be waived). Other comments maintained that it might be difficult to consistently accommodate the information required to be in Highlights within one-half page. These comments stated that the final rule should allow for some flexibility in the length of Highlights in those cases where one-half page may not be practical or possible. These comments indicated that some manufacturers had done mockups of Highlights and had been unable to get the required information on one-half page. Some comments stated that the length restriction should be flexible enough to accommodate as many disclaimers and qualifying messages as are necessary to guide the physician to the more detailed discussion of the desired information in the FPI. These comments maintained that the limitation on length could result in increased medication errors because important information would be too compressed or might be excluded from Highlights.

The agency believes that a one-half page Highlights is adequate for the vast majority of products. As discussed previously, Highlights provides introductory information to the more detailed FPI. The agency does not agree that multiple disclaimers or qualifying statements would be useful or appropriate.

The agency acknowledges, however, that there may be situations in which it may not be possible to accommodate all the information that should go into Highlights within one-half page. In such cases, the agency may waive the one-half page requirement and approve the labeling with slightly longer Highlights. Accordingly, FDA has revised § 201.58 in this final rule to make clear that FDA can waive any of the requirements under § 201.56 or § 201.57.

The agency strongly believes that limiting the length of Highlights is critical to preserving its usefulness. In the physician surveys relied on by the agency in developing and refining the new labeling format, 80 percent of physicians indicated that a summary or highlights section should be no more than one-half page. The surveys found that the perceived usefulness of Highlights declined considerably with increasing length. Accordingly, the labeling format was designed to accommodate, on a single page, a one-

half page Highlights and a one-half page Contents. To test the feasibility of limiting Highlights to one-half of a page, the agency did numerous mockups of Highlights for a wide range of products and found that the one-half page limit provided adequate space in each case. Thus, the agency anticipates that the length restriction will be feasible in the vast majority of cases.

(Comment 105) In the proposal, the agency specifically sought comment on whether there are means other than a vertical line that would facilitate access to, and identification of, new labeling information in the FPI.

Some comments agreed that it was highly desirable to call attention to new information in the FPI and that the vertical line is adequate to identify the new information. Other comments stated that it was desirable to call attention to new information, but that a vertical line in the FPI might not be the best mechanism because it might not be understood as a revision mark by practitioners. Some comments maintained that use of a vertical line would make the printing and graphics process for labeling more complex and costly. One comment recommended italicizing new or revised text in the FPI. One comment recommended use of an asterisk to identify changes, along with a footnote explaining what was changed. Some comments maintained that identifying recent changes in narrative in a section of the FPI devoted to labeling changes or in the proposed ''Recent Labeling Changes'' section in Highlights (now called ''Recent Major Changes'') would alone be adequate to call attention to changes in the FPI. Some comments stated that the vertical line will call unnecessary attention to minor changes. Some comments stated that, by stressing labeling changes, the identification of changes in the FPI could dilute the significance of unmarked text.

The agency has retained the proposed requirement at § 201.57(d)(9) to mark major changes in the FPI with a vertical line in the left margin. The agency agrees that it is highly desirable to call attention to new information in the FPI and that the vertical line is adequate to identify the new information. The agency considered bolding, underlining, and italicizing as means to emphasize changes. These formatting techniques are all currently used in labeling to add emphasis for purposes other than identifying new information, so they would not be readily understood as identifying labeling changes. Asterisks are also used in labeling for purposes other than identifying labeling changes. The agency believes that use of an explanatory footnote with the asterisk would not overcome the confusion arising from use of an asterisk for multiple purposes in labeling.

The agency acknowledges that a vertical line in the margin might not be universally understood as an indication that the text adjacent to the mark has been changed. The agency believes, however, that a significant percentage of practitioners have had some experience with commercial word processing software and thus some exposure to revision marks, including the use of the vertical line to identify changed text. The agency also intends to develop for practitioners a comprehensive educational campaign to accompany the introduction of the revised labeling format. This educational campaign will address, among other issues, the significance of the vertical line in the margin.

The agency does not believe the vertical line will unnecessarily call attention to minor changes in labeling. The vertical line will be applied only to substantive changes that are identified in the ''Recent Major Changes'' (''Recent Labeling Changes'' in the proposed rule) section in Highlights. In response to comments requesting that the agency clarify what is meant by substantive changes, the agency specified in the final rule that only significant changes in the ''Boxed Warning,'' ''Indications and Usage,'' ''Dosage and Administration,'' ''Contraindications,'' and ''Warnings and Precautions'' sections of the FPI be listed in the ''Recent Major Changes'' section. Nonsubstantive changes such as typographical or editorial changes should not be identified. The agency believes that focusing on substantive changes in only these sections will avoid calling unnecessary attention to minor changes and will ensure that the significance of unmarked text is not diluted.

The agency believes that it would not be adequate to identify labeling changes only in a section of the labeling devoted to changes. The agency believes it is important to also identify the specific text that has been changed so that practitioners will be able to locate changes and access the complete text.

J. Comments on Revisions to Container Labels

In addition to revising its regulations governing the content and format of labeling for prescription drugs, the agency also proposed certain revisions to the information required to appear on prescription drug product labels (proposed § 201.100). The proposed revisions were intended to lessen overcrowding on prescription drug labels by removing certain information from the container label.

Current § 201.100(b)(2) requires that the label on a prescription drug container bear a statement of the recommended or usual dosage. Where it is not possible to present an informative or useful statement about the recommended or usual dosage in the space available on the container label, current § 201.55 states that the requirements of § 201.100(b)(2) may be met by including the statement ''See package insert for dosage information.'' The agency proposed to eliminate § 201.55. The agency also proposed to eliminate the requirement in § 201.100(b)(5) that the label of a prescription drug for other than oral use must bear the names of all inactive ingredients. The agency proposed to eliminate the requirement in § 201.100(b)(7) that the container label bear a statement directed to the pharmacist specifying the type of container to be used in dispensing the product to maintain its identity, strength, quality, and purity. The agency proposed to require instead that these instructions be placed in the ''How Supplied/Storage and Handling'' section of prescription drug labeling (proposed § 201.57(c)(4)(v)).

(Comment 106) Several comments opposed the proposal to eliminate the requirement that the label of a prescription drug product for other than oral use bear the name of all inactive ingredients. The comments stated that identification of inactive ingredients is important because of their potential to be allergens. Some comments maintained that manufacturers should be able to list on product labels selected inactive ingredients (e.g., ingredients that are known allergens or are associated with adverse reactions). One comment recommended listing the diluent that should be used for admixture or those diluents that are contraindicated. Two comments supported eliminating the list of inactive ingredients from the container label of products for other than oral use. They agreed that the presence of such information in the ''Description'' section of prescription drug labeling would be sufficient and that eliminating the information from the container label could make other information on the label more accessible and legible.

Several comments also opposed the proposal to eliminate the requirement that the label of a prescription drug product bear a statement directed to the pharmacist specifying the type of container to be used in dispensing the product to maintain its identity,

strength, quality, and purity. The comments maintained that eliminating dispensing information from the container label, and placing it in prescription drug labeling, would make the information less accessible to pharmacists and would thus be inefficient and frustrating for pharmacists. The comments were concerned that making information on storage and handling less accessible could lead to inappropriate storage and handling. Some comments urged that the label at least be required to state any special or unusual conditions for storage. One comment recommended mandatory use of a symbol that signifies when a product requires special handling. Two comments supported removal of information on storage and handling from product labels, agreeing that less information on the container label could make other information on the label more accessible and legible.

One comment maintained that manufacturers should be able to remove from the label the statement referring practitioners to the full prescribing information for dosage information before the manufacturer is required to revise its label in accordance with this final rule.

The agency has reconsidered its proposals to eliminate from container labels: (1) The list of inactive ingredients for products other than for oral use, (2) the statement directed to the pharmacist concerning the type of container in which a product should be dispensed, and (3) the statement referring practitioners to the package insert for dosage information in situations in which it is not possible to include information about the recommended or usual dose on the label. The agency decided to withdraw these proposed revisions to container labels. The agency believes that what is appropriate content for product container labels and how to make that information as accessible as possible need to be further evaluated. The agency intends to conduct a comprehensive evaluation of information required to be included on container labels and, if necessary, will propose changes to these requirements at that time.

At this time, the agency will not require placement of a symbol on the container label indicating that the product has special storage and handling requirements. The agency will consider this possibility during its evaluation of the content of product labels. It would be premature to adopt such a symbol at this time.

(Comment 107) One comment requested that the proposed requirement to specify in the ''How Supplied/Storage and Handling'' section the type of container to be used in dispensing a product to maintain a product's identity, strength, quality, and purity (information formerly presented on the product label) should apply only if the product cannot be dispensed in the standard amber vial. The comment maintains that limiting the scope of the requirement to situations in which exceptional storage conditions are required would serve to highlight the need for special considerations when dispensing.

As discussed in the previous comment, the agency has reconsidered its proposed changes to the container label, including the proposal to remove from the container label information directed at the pharmacist concerning the appropriate container in which to dispense a product. The agency will continue to require that dispensing instructions appear on the container label. Accordingly, proposed § 201.57(c)(4)(v) was deleted from the final rule. Storage and special handling conditions have to be specified in labeling consistent with the requirements of § 201.57(c)(17)(iv) of this final rule.

(Comment 108) One comment requested that the container label also be required to disclose when the container or some component of the container contains latex or polyvinyl chloride (PVCs).

As discussed in the response to comment 106, the agency intends to conduct a comprehensive evaluation of the product label and may repropose changes in the content of the product label at a later time, including changes concerning the presence of latex and PVCs in drug containers.

(Comment 109) One comment urged that there be a mandatory location for the ''Rx Only'' symbol on the main part of the label and that there be a specified minimum font size for the symbol.

In rulemaking (initiated under section 126 of the Food and Drug Administration Modernization Act of 1997), the agency amended its regulation requiring that container labels contain the statement ''Caution: Federal law prohibits dispensing without prescription'' by replacing the statement with the symbol ''Rx Only'' (67 FR 4904, February 1, 2002). Comments submitted to the agency in response to this proposed change requested that FDA specify the font size and the location of the symbol on the container label. The agency declined this request in the final rule of February 1, 2002, and declines it again in this final rule. As discussed in the preamble to the February 2002 final rule, existing statutory (section 502(c) of the act) and regulatory provisions (§ 201.15) requiring that information on product labels be prominent and conspicuous so as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use provide the agency adequate authority to ensure that the symbol is visually accessible. The agency does not believe it is necessary to specify the location of the symbol or its font size to ensure that the symbol achieves adequate prominence.

(Comment 110) One comment expressed concern about the proliferation of artwork on label containers and the potential for that artwork to make the label more difficult to read and cause medication errors.

The agency acknowledges the potential for artwork to obscure important information on the label. The agency believes, however, that its existing authority under 502(c) of the act and § 201.15 is adequate to ensure that artwork does not compromise the prominence and conspicuousness of information required to be on the label.

K. Miscellaneous Comments

(Comment 111) One comment requested that the agency clarify how the content and format of the brief summary required to accompany prescription drug advertising under § 202.1 would be affected by the proposed revisions to prescription drug labeling. Another comment suggested that the agency entertain the idea that Highlights could serve as an alternative to the brief summary because the agency has noted that Highlights contains the most important information about drug-related risks.

The proposed regulations were not designed to affect either the content or the format of the brief summary of prescribing information required to accompany prescription drug advertisements under § 202.1 (21 U.S.C. 352(n)). As discussed in the proposed rule (65 FR 81082 at 81087), statements made in promotional labeling and advertisements must be consistent with all information included in labeling under proposed § 201.57(c) to comply with current §§ 201.100(d)(1) and 202.1(e).[9] The agency does believe, however, that Highlights communicates important information about a drug. The agency therefore will explore further, in conjunction with other prescription drug advertising initiatives, the concept

[9] This requirement at proposed § 201.57(a) has been removed because it is not pertinent to the contents of § 201.57 and is redundant with provisions at §§ 202.1 and 201.100.

that Highlights could serve as a brief summary (see also FDA's response to comment 112 about the brief summary for consumer directed advertisements).

(Comment 112) Some comments stated that prescription drug labeling should be written in language that a lay audience can comprehend. The comments noted that consumers need to be able to read and understand the labeling because it accompanies the product, and because it is often used to provide information for direct-to-consumer (DTC) advertisements.

The purpose of prescription drug labeling is to provide health care practitioners information necessary for safe and effective use. The agency believes that use of medical and scientific terminology is necessary to effectively communicate to practitioners information about a product's risks and benefits as required under 21 U.S.C. 352(n) and § 201.100. Requiring that language used in prescription drug labeling be tailored to a lay audience would result in a loss of the clarity and precision needed to effectively communicate to practitioners a product's benefits and risks. For example, if a drug is associated with a risk of a specific type of blood disorder, the disorder must be identified by its technical name (e.g., thrombotic thrombocytopenic purpura) so the practitioner can more quickly diagnose and treat the disorder when symptoms present. Scientific terminology may help to identify types of patients that might be at increased risk or otherwise manage the risk of that blood disorder. If the risk can only be described in terms that a lay audience can comprehend (e.g., blood disorder), the labeling would lack the precision needed to communicate the specific risk to prescribers.

For many products, the final rule will improve the usefulness of the brief summary to consumers and health care practitioners by improving the usefulness of the prescription drug labeling, on which the brief summary is based. To this end, FDA has issued a draft guidance document entitled ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements'' that describes various options for presenting this information in DTC print advertisements (69 FR 6308, February 10, 2004). By providing recommendations on use of alternatives to prescription drug labeling to fulfill the brief summary requirement, FDA is encouraging manufacturers to develop brief summaries for use in consumer-directed advertisements using language they can understand.

L. Comments on the Proposed Implementation Plan

For new and more recently approved drugs, FDA proposed a staggered implementation schedule for the labeling requirements, with revised labeling required for newer products first (proposed § 201.56(c)). The schedule is being finalized as proposed (see table 5 in section III of this document). Revised labeling for ANDA products depends on the labeling for the reference listed drug. The agency proposed to implement no later than 1 year after the effective date of the final rule the revised content requirements regarding unsubstantiated claims in labeling for newer and older drugs. The agency also proposed to implement by 1 year after the effective date of the final rule the requirement that any FDA-approved patient labeling be reprinted immediately following the ''Patient Counseling Information'' section of the FPI for newer products or immediately following the last section of the labeling for older products. The agency also proposed to implement by 1 year after the effective date of the final rule the requirement that in vitro or animal data related to activity or efficacy of a drug that have not been shown by adequate and well-controlled studies to be pertinent to clinical use be removed from the labeling unless a waiver is granted.

In the proposal, the agency specifically sought comment on whether the revised content and format requirements should be applied, as proposed, to drug products with an NDA, BLA, or efficacy supplement that is pending at the effective date of the final rule, that was submitted on or after the effective date of the final rule, or that has been approved from 0 up to and including 5 years prior to the effective date of the final rule, or whether alternative application criteria should be used.

(Comment 113) Several comments agreed with the categories of prescription drugs that would be subject to the new labeling content and format requirements in the agency's proposed implementation plan. Other comments expressed concern that the proposed implementation plan is too narrow. These comments maintained that the new format is superior to the old format and the scope of the proposed implementation of the new format would leave large numbers of products with inferior labeling. Some comments requested that the revised content and format requirements eventually be applied to all marketed prescription drugs. One comment recommended that the implementation plan also apply to all drugs that are among the 150 most frequently prescribed drugs that would not otherwise be covered by the implementation plan. The comment maintained that under the proposed implementation plan only 1 of the current top 15 drugs used in the elderly would be required to implement the revised content and format.

Some comments expressed concern that having different labeling formats would be confusing to physicians. One comment expressed concern that having two different formats might impact prescribing behavior, arguing that prescribers might favor newer, more expensive drugs. Some comments maintained that a single standard format is needed to facilitate access to labeling in electronic formats. One comment also questioned FDA's underlying assumption that there is a lesser need for improved labeling for older products because practitioners are more familiar with older products and refer to older product labeling less frequently than newer product labeling. The comment maintained that newer practitioners would need to refer to the labeling of older drugs to the same extent as for newer drugs. One comment suggested that manufacturers be given the option to revise labeling for older products.

Some comments from manufacturers maintained that it would be most practical to apply the new format requirements only to products whose applications are submitted on or after the effective date of the final rule. They stated that broader implementation would place a substantial burden on FDA resources and could interfere with review of new drugs. One comment stated that the new format should apply only to drugs that are not a member of an existing drug class (i.e., products that would be considered the original member of a drug class) or that are a new and novel member of an existing drug class and whose applications are submitted on or after the effective date of the final rule. The comment maintained that having different labeling formats for similar drugs within the same drug class would be a competitive disadvantage for one format or the other.

The agency believes the implementation plan as proposed for new and more recently approved drug products is the best option for implementing the new format requirements. The agency agrees that it is desirable for all prescription drugs to be subject to the same labeling rules. However, the agency has carefully considered the costs and benefits of implementing the revised labeling

format and determined that requiring broader implementation (e.g., to all prescription drugs) of the new format requirements would be an excessive regulatory burden.

This initiative will require substantial resource allocation by the agency and industry for a period of several years. The agency's proposed implementation plan, which is being finalized in this rule as proposed, is intended to make the best use of these resources. As discussed in the preamble to the proposed rule (65 FR 81082 at 81098), the plan targets newer products because practitioners are more likely to refer to the labeling for newer products. In FDA's survey of physicians, newness of the product was a reason rated by 87 percent of physicians as very likely to trigger a labeling referral for a drug (Ref. 11, p. 35). In addition, the labeling for newer products is typically longer and more complex and, thus, more likely to benefit from a new format that makes the information more accessible. The implementation plan will also capture many older products that would not otherwise be covered by the plan when manufacturers seek new indications for their products (i.e., submit an efficacy supplement). For these reasons, the agency believes the implementation as proposed is the most reasonable approach to maximizing the public health benefit and best utilizing available resources in requiring the new content and format for labeling. In addition, manufacturers of older products not covered by the implementation plan may voluntarily revise, and submit for review, labeling for their products in the new format at any time.

The agency does not believe that an implementation plan based on volume of prescriptions would be prudent. Prescription volume can fluctuate considerably over time, and the agency is not aware that there are standardized prescription volume data that are generally accepted as accurate. Thus, the agency believes it would be very difficult to fairly implement and enforce an implementation plan based on prescription volume.

The agency also acknowledges that the existence of two different labeling formats may lead to some frustration among practitioners. The agency believes, however, that any potential confusion can be minimized. Practitioners are already aware of the content and format of existing labeling. The agency intends to engage in a comprehensive educational campaign to educate practitioners about the major features of the new format and why the implementation plan did not encompass all prescription drugs.

FDA is cognizant that the presence of two labeling formats will present important challenges when implementing electronic labeling but is confident that these challenges can be successfully addressed. For example, the ways in which information will be formatted, tagged, and stored in the contemplated electronic format will permit access to labeling information in both the old and new labeling formats.

The agency does not agree that the new format should be applied only prospectively or that it should be optional for the currently approved drugs that would be subject to the new format requirements under the proposed implementation plan. This narrower application of the new format requirements would fail to reach a significant number of products whose labeling is frequently referenced and could benefit from the new format requirements.

(Comment 114) Several comments objected to the proposed requirement that, within 1 year of the effective date of the final rule, manufacturers review all existing labeling and remove any express or implied unsubstantiated claims from the ''Indications and Usage,'' ''Dosage and Administration,'' ''Clinical Pharmacology,'' and ''Clinical Studies'' sections. Some comments maintained that this requirement would be very burdensome for industry and the agency. They disagreed with the agency's contention in the preamble to the proposed rule that the labeling changes to remove unsubstantiated claims could usually be accomplished without prior approval by the agency (i.e., with a ''Changes Being Effected'' labeling supplement). They stated that these changes would more often than not require prior approval and extensive negotiations between the agency and a manufacturer. Some comments maintained that there would be a substantial number of requests for waivers under § 201.58 or § 314.126(c) and these requests would also be a burden on the agency. Some comments agreed with the requirement to remove unsubstantiated claims from existing labeling, but stated that 1 year was not enough time for manufacturers to accomplish the task. One comment maintained that the burden on the agency would compromise the drug approval process. One comment requested that the agency clarify what types of statements would have to be removed.

The agency has reconsidered the proposed requirement to have manufacturers scrutinize all existing labeling for unsubstantiated claims and remove all such claims from labeling within 1 year of the effective date of the final rule. The agency agrees that a requirement to scrutinize all existing labeling within that timeframe would place substantial burdens on manufacturers and the agency and that such burdens might not be justified. In the preamble to the proposed rule, the agency estimated that no more than 25 percent of labeling for drugs other than antibiotics might contain unsubstantiated claims. Based on a recent review of a sample of prescription drug labeling, however, the agency believes the percentage of products whose labeling might contain such claims is considerably lower than 25 percent and not high enough to justify a requirement that manufacturers scrutinize all existing labeling to identify those claims, particularly in a short timeframe.

The agency is eliminating only the requirement that manufacturers scrutinize all labeling for the presence of unsubstantiated claims within 1 year of the effective date of the final rule. The language in proposed § 201.57(c)(2), (c)(3), and (c)(15) and § 201.80(c)(2), (j), and (m)(1) remains in the final rule, requiring that the ''Indications and Usage,'' ''Dosage and Administration,'' and ''Clinical Studies'' sections must not imply or suggest uses not supported by substantial evidence and/or dosing regimens not included in the ''Dosage and Administration'' section. This language accurately reflects the existing regulatory standard for claims presented in prescription drug labeling.

While the agency will not require a systematic evaluation of all existing labeling to identify unsubstantiated claims within 1 year of the effective date of the final rule, the agency wishes to make it clear that manufacturers have an ongoing obligation to ensure that claims in labeling have adequate substantiation and are not false or misleading. When new information comes to light that causes information in labeling to become inaccurate, manufacturers must act to change the content of their labeling, in accordance with §§ 314.70 and 601.12 (21 CFR 314.70 and 21 CFR 601.12). To clarify this obligation, the agency has revised § 201.56 to specify that manufacturers must act to correct labeling that, in light of new information, has become inaccurate (see § 201.56(a)(2)).

(Comment 115) One comment recommended an implementation period of 3 years, rather than 1 year as proposed, to append any FDA-approved patient labeling to the end of the labeling for trade packages. The

comment maintained that additional time was needed for reconfiguration and replacement of packaging equipment.

The agency believes that the proposed implementation plan is appropriate and in the best interest of public health. Including the FDA-approved patient labeling in prescription drug labeling ensures that this information is available to health care practitioners to reinforce the discussions they have with their patients concerning the risks and benefits of prescription drugs. The agency considers improving physician-patient communication crucial for public health. Furthermore, the agency believes that this requirement should not place an undue burden on manufacturers because of the approximately 200 products that would be affected by this provision of the final rule, the labeling of more than 60 percent of them already conform with the requirement (see section XI.C.1 of this document).

(Comment 116) Manufacturers of products subject to an ANDA (generic products) expressed concern that NDA holders will use the rule's implementation provisions as a mechanism to delay approval of generics. The specific concern was that NDA holders will obtain approval for a new indication near the end of their marketing exclusivity for their drug's original indication, revise the labeling for the drug to the new format, and receive 3 years' marketing exclusivity for the new indication. The comments asked FDA to make it clear that, in such situations, manufacturers of generic products would be permitted to base their labeling on the old format until the marketing exclusivity for the new indication has expired.

The agency wishes to make clear that the requirement to revise the labeling of a reference listed drug in the new format does not have any impact on the duration of exclusivity for the drug and, therefore, does not prevent a manufacturer of a generic product from using the revised labeling of the reference listed drug. Under section 505(j)(2)(A)(v) of the act (21 U.S.C. 355(j)(2)(A)(v)) and §§ 314.94(a)(8) and 314.127(a)(7) (21 CFR 314.127(a)(7)) of the agency's regulations, the labeling of a drug product submitted for approval under an ANDA must be the same as the labeling of the listed drug referenced in the ANDA, except for changes required because of differences approved under a suitability petition (§ 314.93), because the generic drug product and the reference listed drug are produced or distributed by different manufacturers, or because aspects of the listed drug's labeling are protected by patent or exclusivity. This final rule does not change the requirement to exclude any condition of use or indication from the labeling of a generic product when necessary (e.g., when the reference listed drug has patent protection or market exclusivity for an indication), nor does it prevent, as described at § 314.127(a)(7), approval of an ANDA when the reference listed drug has protected labeling.

In the scenario described, the reference listed drug and the generic product would both be required to use the new labeling format. The NDA holder could not prevent the manufacturer of the generic product from using the new labeling format of the reference listed drug, but the NDA holder would still have exclusivity for the new indication.

(Comment 117) One comment recommended that all generic drugs pending approval or approved on or after the effective date of the final rule be required to submit labeling based on the new format. The comment maintained that the content of labeling is not significantly changed, just reordered, so this requirement would not be burdensome for manufacturers of generic products and the information in the labeling of the reference listed drug product and the generic product would still be essentially the same.

The agency does not believe that manufacturers of generic products should be required to provide labeling in the new format when seeking approval for their product if the reference listed drug product is not required to have its labeling in the new format. As discussed in the response to comment 115, the act and regulations currently require that a generic product have the same labeling as the reference listed drug product. Moreover, the agency believes that, to avoid confusion, the labeling of a generic product should be in the same format as the labeling of the reference listed drug.

(Comment 118) One comment urged FDA to compile a list of products that would be subject to the new format requirements and make the list publicly available.

FDA does not believe that it is necessary to compile such a list. Manufacturers can readily determine whether their products are subject to these requirements by referring to the implementation plan and the effective date of the rule (see section III of this document).

(Comment 119) Some comments requested that the agency clarify whether this final rule has implications for labeling that is distributed with prescription drug samples. One comment requested that the agency amend the rule to include labeling that is distributed with prescription drug samples. The comment maintained that free prescription drug samples do not contain adequate information in their packaging to keep consumers safe from harm.

FDA has often emphasized the importance of providing patients with useful written prescription drug information (e.g., FDA-approved patient labeling) in a variety of settings (see e.g., 63 FR 66378, December 1, 1998; 68 FR 33724, June 5, 2003). Prescription drug samples must be accompanied by trade labeling (§ 201.100(c)), which is subject to this final rule. If FDA-approved patient labeling for a product is required to be distributed to the patient, the manufacturer or distributor of that product must provide it with the samples.

M. Comments on Environmental Impact

(Comment 120) One comment maintained that FDA failed to adequately consider the environmental impact of the additional paper that will be required for labeling and the increase in size of packaging and shipping containers.

As stated in section IX of the proposed rule (65 FR 81082 at 81103), the agency determined that it is not required to do an environmental assessment or an environmental impact statement. This is an action excluded under § 25.30(h) and (k) (21 CFR 25.30(h) and (k)) (i.e., does not individually or cumulatively have a significant effect on the human environment). The changes made to the proposal in this final rule do not change this conclusion. Therefore, neither an environmental assessment nor environmental impact statement is required.

VII. Legal Authority

In this rule, FDA is addressing legal issues relating to the agency's action to revise the regulations prescribing content and format requirements for prescription drug labeling.

A. Statutory Authority

FDA's revisions to the content and format requirements for prescription drug labeling are authorized by the act and by the Public Health Service Act (the PHS Act). Section 502(a) of the act deems a drug to be misbranded if its labeling is false or misleading ''in any particular.'' Under section 201(n) of the act, labeling is misleading if it fails to reveal facts that are material with respect to consequences which may result from the use of the drug under the

conditions of use prescribed in the labeling or under customary or usual conditions of use. Section 502(f) of the act deems a drug to be misbranded if its labeling lacks adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, as well as adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. Section 502(j) of the act deems a drug to be misbranded if it is dangerous to health when used in the dosage or manner, or with the frequency or duration, prescribed, recommended, or suggested in its labeling.

In addition, the premarket approval provisions of the act authorize FDA to require that prescription drug labeling provide the practitioner with adequate information to permit safe and effective use of the drug product. Under section 505 of the act, FDA will approve an NDA only if the drug is shown to be both safe and effective for use under the conditions set forth in the drug's labeling. Section 701(a) of the act (21 U.S.C. 371(a)) authorizes FDA to issue regulations for the efficient enforcement of the act.

Under 21 CFR 314.125, FDA will not approve an NDA unless, among other things, there is adequate safety and effectiveness information for the labeled uses and the product labeling complies with the requirements of part 201. Under § 201.100(d) of FDA's regulations, prescription drug products must bear labeling that contains adequate information under which licensed practitioners can use the drug safely for their intended uses. This final rule amends the regulations specifying the format and content for such labeling.

Section 351 of the PHS Act (42 U.S.C. 262) provides legal authority for the agency to regulate the labeling and shipment of biological products. Licenses for biological products are to be issued only upon a showing that they meet standards ''designed to insure the continued safety, purity, and potency of such products'' prescribed in regulations (section 351(d) of the PHS Act). The ''potency'' of a biological product includes its effectiveness (21 CFR 600.3(s)). Section 351(b) of the PHS Act prohibits false labeling of a biological product. FDA's regulations in part 201 apply to all prescription drug products, including biological products.

B. First Amendment

FDA's requirements for the content and format of prescription drug labeling are constitutionally permissible because they are reasonably related to the government's interest in ensuring the safe and effective use of prescription drug products and because they do not impose ''unjustified or unduly burdensome'' disclosure requirements. (See *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985); see also *Ibanez* v. *Florida Dep't of Bus. and Prof'l Regulation*, 512 U.S. 136, 146 (1994).) The information required by the final rule to appear in labeling is the information necessary to provide facts that are material with respect to consequences which may result from the use of the drug under the conditions of use prescribed in the labeling or under customary or usual conditions of use (sections 201(n) and 502(a) of the act); adequate directions for use and adequate warnings (section 502(f) of the act); and information on the conditions of use in which the product would be dangerous (section 502(j) of the act). In addition, pursuant to section 505 of the act, the labeling sets forth information on the conditions in which the product is safe and effective. By its terms, the final rule requires disclosure of the essential scientific information necessary for safe and effective use of the labeled drug product. Consequently, FDA believes the final rule passes muster under the First Amendment.

In *Central Hudson Gas & Electric Corporation* v. *Public Service Commission* 447 U.S. 557 (1980), the Supreme Court established a four-step analysis for assessing the constitutionality of government restrictions on the content of commercial speech.

> [First,] we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. [Second,] we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine [third] whether the regulation directly advances the government interest asserted, and [fourth,] whether it is not more extensive than is necessary to serve that interest.

This rule also survives scrutiny under the four-part test in *Central Hudson*. FDA believes that much information required to appear in prescription drug labeling is necessary for labeling to be nonmisleading. The risk information contained in such labeling, for example, constitutes material facts within the meaning of sections 201(n) and 502(a) of the act. Risk information can also qualify as warnings compelled by section 502(f) and (j) of the act. Other information, such as information on indications for the product, dosage and administration information, and how supplied information, is necessary because it provides adequate directions for use. Because not all of the information required in labeling clearly is necessary to prevent the labeling from being false or misleading, it is necessary for FDA to apply the remaining parts of the *Central Hudson* analysis.

FDA's interest in protecting the public health has been previously upheld as a substantial government interest under Central Hudson. (See *Pearson* v. *Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999) (citing *Rubin* v. *Coors Brewing Co.*, 514 U.S. 476, 484–85 (1995).) The final rule's labeling requirements directly advance this interest, thereby satisfying the third part of *Central Hudson*, because by requiring disclosure of complete information on the conditions under which a product can be used safely and effectively, the requirements help to ensure that prescription drug products will be prescribed properly by health care practitioners and will be used safely and effectively by patients.

Finally, under the fourth part of the *Central Hudson* test, there are not numerous and obvious alternatives (in fact, there are no reasonable alternatives) (*Cincinnati* v. *Discovery Network*, 507 U.S. 410, 418 n.13 (1993)) to the content and format requirements of this final rule that directly advance the government's interest but are less burdensome to speech. Health care practitioners are accustomed to looking to the prescription drug labeling as their primary source of information about a product, and patients rely for their drug information primarily on practitioners. Neither a public education campaign, nor encouraging sponsors to provide information on the risks and benefits of drugs but not requiring such information, would ensure that practitioners have the information they need about the conditions in which prescription drugs can be used safely and effectively. Requiring disclosures meets the fourth part of the test.

Accordingly, the agency believes it has complied with its burdens under the First Amendment to support the content and format requirements for prescription drug labeling.

VIII. Paperwork Reduction Act of 1995

The final rule contains information collection provisions that are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description and respondent description of the information collection provisions are shown below with an estimate of the reporting burdens. Included in the estimate is the time for reviewing

instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. The OMB and FDA received no comments concerning the information collection provisions of the proposed rule.

Title: Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

Description: The final rule amends FDA's regulations governing the format and content of labeling for human prescription drug products. It revises current regulations to require that the labeling of new and recently approved products contain highlights of prescribing information, a table of contents for prescribing information, reordering of certain sections, minor content changes, and minimum graphical requirements. The final rule does not subject older drugs to the revised labeling requirements. However, it does require, as for new and recently approved products, that FDA-approved patient labeling accompany or be reprinted immediately following the last section of prescription drug labeling.

As discussed in section VII of this document, FDA's legal authority to amend its regulations governing the content and format of labeling for human prescription drugs derives from sections 201, 301, 502, 503, 505, and 701 of the act and from section 351 of the PHS Act.

A. Summary of Prescription Drug Labeling Content and Format Requirements in this Final Rule That Contain Collections of Information

Section 201.56 requires that prescription drug labeling contain certain information in the format specified in either § 201.57 or § 201.80, depending on when the drug was approved for marketing. Section 201.56(a) sets forth general labeling requirements applicable to all prescription drugs. Section 201.56(b) specifies the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in §§ 201.56(d) and 201.57. Section 201.56(c) sets forth the schedule for implementing these revised content and format requirements. Section 201.56(e) specifies the sections and subsections, required and optional, for the labeling of older prescription drugs not subject to the revised format and content requirements.

Section 201.57(a) requires that prescription drug labeling for new and more recently approved prescription drug products include ''Highlights of Prescribing Information.'' Highlights provides a concise extract of the most important information required under § 201.57(c) (the FPI), as well as certain additional information important to prescribers. Section 201.57(b) requires a table of contents to prescribing information, entitled ''Full Prescribing Information: Contents,'' consisting of a list of each heading and subheading along with its identifying number to facilitate health care practitioners' use of labeling information. Section 201.57(c) specifies the contents of the FPI. The final rule reorders information required at former § 201.57, makes minor content changes, and provides standardized identifying numbers for the required information. Section 201.57(d) mandates new minimum specifications for the format of prescription drug labeling and establishes minimum requirements for key graphic elements such as bold type, bullet points, type size, and spacing.

In accordance with the final rule, older drugs not subject to the revised labeling content and format requirements in § 201.57 remain subject to labeling requirements at former § 201.57, which is redesignated as § 201.80 by this final rule. Section 201.80 contains minor clarifications. In addition, § 201.80(f)(2) requires that within 1 year, any FDA-approved patient labeling be referenced in the ''Precautions'' section of the labeling of older products and either accompany or be reprinted immediately following the labeling.

B. Estimates of Reporting Burden

1. The Reporting Burdens for the General Requirements (§ 201.56)

The reporting burdens for the general requirements in § 201.56(a) are the same as those for former § 201.56(a) through (c) and are estimated in tables 8a and 8b as part of the burdens associated with § 201.57. Section 201.56(b) and (c) sets forth the categories of affected drugs and their implementation schedule, generating no reporting burdens. Section 201.56(d) sets forth the required sections and subsections associated with the revised format in § 201.57; therefore, its associated reporting burdens are estimated in tables 8a and 8b under the requirements at § 201.57. Sections 201.56(e) and 201.80 codify former labeling requirements at §§ 201.56(d) and (e) and 201.57, with minor clarifications, for older prescription drugs. The requirements in these sections impose no new reporting burdens (except those accounted for in section VIII.B.6 of this document), as they were previously incurred to produce existing labeling.

2. Annual Burden for Labeling Design, Testing, and Submitting to FDA for NDAs Submitted on or After the Effective Date of the Final Rule (§§ 201.56 and 201.57)

New drug product applicants must: (1) Design and create prescription drug labeling containing Highlights, Contents, and FPI, (2) test the designed labeling (e.g., to ensure that the designed labeling fits into carton-enclosed products), and (3) submit it to FDA for approval.

Based on information received from the pharmaceutical industry, FDA estimated that it took applicants approximately 3,200 hours to design, test, and submit prescription drug labeling to FDA as part of an NDA or BLA under former labeling requirements (see row 1 of table 8a). FDA estimates that it will take an additional 149 hours to generate Highlights and Contents and otherwise comply with the additional requirements of the final rule (see row 2 of table 8a). Therefore, it will take a total of approximately 3,349 hours to design, test, and submit new labeling. Approximately 85 applicants would submit approximately 107 new applications (NDAs and BLAs) to FDA per year, totaling 358,343 hours (see Total of table 8a).

3. Burden Associated with Labeling Supplements for Applications Approved Within 5 Years Prior to the Effective Date of the Rule (§ 201.57)

The final rule requires that prescription drug applications approved during the 5 years before, or pending on, the effective date conform to format and content requirements at § 201.57. For these products, applicants must redesign and negotiate the labeling, including Highlights and Contents, test the redesigned labeling, and prepare and submit that labeling to FDA for approval. Based on information provided in the ''Analysis of Economic Impacts'' (economic analysis) (see section XI.D.2.a of this document), labeling supplements for a total of approximately 344 innovator products would be submitted to the FDA over a 5-year period (beginning in year 3 and ending in year 7 after the effective date of the rule). Approximately 172 applicants would submit these labeling supplements. The time required for redesigning, testing, and submitting the labeling to FDA is estimated to be approximately 196 hours per application, totaling 67,424 hours (see row 1 of table 8b).

4. Burden Associated with Revised Labeling Efficacy Supplements Submitted on or After the Effective Date of the Rule (§§ 201.56(d) and 201.57)

Efficacy supplemental applications for older drugs submitted on or after the effective date of the final rule are subject to the content and format requirements at §§ 201.56(d) and 201.57. To meet these requirements, applicants must revise the existing labeling for these products. Each year an increasing number of innovator drug labeling will have been revised, and over time, very few efficacy supplements independently will generate labeling revisions as a result of this final rule. According to information in the economic analysis, the total number of affected efficacy supplements over 10 years is estimated at 324, with a decreasing number each year over the 10-year period (see section XI.D.2.a. of this document). For purposes of this analysis, the total burden for efficacy supplements is summarized in row 2 of table 8b. Over 10 years, approximately 172 applicants will trigger approximately 324 efficacy supplements, each one requiring approximately 196 hours to revise the labeling in the application, totaling 63,504 hours. In addition to this burden, a minimal annual reporting burden, probably even lower than the 7 per year estimated in year 10 of table 13 of this document, will continue indefinitely.

5. Burden Associated with Revised Labeling for Efficacy Supplements for Generic Drug Products (§ 201.57)

The reporting burden for generic products subject to the requirements of the final rule has only been estimated for those products requiring revisions to their existing labeling. Reporting burdens for generating newly approved labeling for generic products (§ 314.94(8)) is already approved under OMB control number 0910–0001. According to the data in the economic analysis, beginning in year 3 and continuing throughout the 10-year period analyzed, approximately 42 generic applications per year must submit labeling supplements to comply with the final rule (see section XI.D.2.a of this document). For purposes of this analysis, approximately 336 already approved generic drug applications must submit labeling supplements over the 10-year period after the effective date of the rule (see section XI.D.2.a of this document). The time required to revise and submit this labeling to FDA would be approximately 27 hours per application, totaling 9,072 hours (see row 3 of table 8b). In addition to this burden, a minimal reporting burden associated with a very small number of generic applications referencing older drugs may continue indefinitely.

6. Requirement That FDA-Approved Patient Labeling Accompany Prescription Drug Labeling Within 1 Year (§§ 201.57 and 201.80)

Within 1 year, all FDA-approved patient labeling must either accompany or be reprinted immediately following the prescription drug labeling (§§ 201.57(c)(18) and 201.80(f)(2)). As indicated in the economic analysis (section XI.D.1 of this document), an estimated 80 products will need to revise labeling as a result of this requirement. Approximately 18 applicants would be subject to this requirement. The agency estimates approximately 38 hours per product as a one-time labeling revision, totaling 3,040 hours (see row 4 of table 8b).

C. Capital Costs

A small number of carton-enclosed products may require new packaging to accommodate longer inserts (see section XI.D.2.c and comment 124 of this document). As described in more detail in the economic analysis (section XI.D.2.c.ii), up to 5 percent of the existing products affected by the rule (i.e., products with new efficacy supplements, products approved in the 5 years prior to the effective date of the rule, and affected ANDAs) may require equipment changes at an estimated cost of $200,000 each product. As shown in table 17, the estimated value of equipment changes totals $7.2 million and $8.7 million over 10 years discounted at 7 and 3 percent, respectively.

Description of Respondents: Persons and businesses, including small businesses and manufacturers.

TABLE 8A.—ESTIMATED REPORTING BURDEN FOR NEW DRUG APPLICATIONS[1]

Category (21 CFR section)	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Annual burden associated with former labeling requirements (former 201.56(d) and 201.57)	85	1.26	107	3,200	342,400
Additional annual burden associated with requirements of this final rule (201.56(d) and 201.57)	85	1.26	107	149	15,943
Total				3,349	358,343

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 8B.—ESTIMATED REPORTING BURDENS FOR LABELING REVISIONS TO ALREADY-APPROVED DRUG PRODUCTS[1]

Category (21 CFR section)	Year(s) In Which Burdens Occur Following Rule's Effective Date	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Response	Total Hours	Total Capital Costs
Burden associated with revised labeling for applications approved within 5 years prior to the rule's effective date (201.57)	Beginning year 3, ending year 7	172	2.0	344	196	67,424	$3.3 million
Burden associated with revised labeling for efficacy supplements submitted on or after the rule's effective date (201.56(d) and 201.57)	Beginning year 1, diminishing over time	172	1.88	324	196	63,504	$2.5 million
Burden associated with revised labeling for efficacy supplements for generic drug products (201.57)	Beginning year 3, continuing annually thereafter	42	8	336 (for years 1–10)	27	9,072	$2.5 million
Burden as a result of having FDA-approved patient labeling accompany drug labeling within 1 year (201.57(c)(18) and 201.80(f)(2))	Year 1 only	18	4.44	80	38	3,040	$400,000
Total						143,040	Up to $8.7 million (see table 17)

[1] There are no operating and maintenance costs associated with this collection of information.

The information collection provisions in this final rule have been approved under OMB control number 0910–0572. This approval expires December 31, 2008. 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.

IX. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (k) 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.

X. Executive Order 13132: Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''[10] Here, FDA has determined that the exercise of State authority conflicts with the exercise of Federal authority under the act.

The act gives FDA comprehensive authority over drug safety, effectiveness, and labeling. FDA is the expert Federal agency charged by Congress with ensuring that drugs are safe and effective and that product labeling is truthful and not misleading (sections 505(d) and 903(b)(2)(B) of the act (21 U.S.C. 393(b)(2)(B))). According to the act, a manufacturer of a drug must submit an NDA containing ''full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use'' (section 505(b)(1)(A) of the act; see also 21 CFR 314.50; see also *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979) (''Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk. Thus, the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use'' (citations omitted))).

[10] Because we have determined that the act preempts State law because the exercise of State authority conflicts with the exercise of Federal authority under that statute, we need not construe our statutory rulemaking authority as required by section 4(b) of the Executive order.

An NDA must include the ''proposed text of the labeling,'' together with ''annotations to the information in the summary and technical sections of the application that support the inclusion of each statement in the labeling * * *'' (21 CFR 314.50(c)(2)(i)). The proposed labeling must also provide ''adequate directions for use'' (section 502(f) of the act). FDA by regulation has defined this to mean ''directions under which the layman can use a drug safely * * *'' (21 CFR 201.5). Because a prescription drug, by definition, cannot be used safely by a layperson without professional supervision, FDA regulations afford an exemption from the statutory requirement of adequate directions for use for a prescription drug whose labeling includes ''any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended * * *'' (§ 201.100(c)(1)). If labeling lacks this information, or is otherwise false or misleading in any particular, FDA is authorized to refuse to approve the NDA (section 505(d) of the act; 21 CFR 314.125(b)(6) and (b)(8)).

The FDA review process for an NDA is thorough and scientifically rigorous. An NDA must contain proposed labeling and all information about the

drug (whether favorable or unfavorable) that is pertinent to evaluating the application and that is received or otherwise obtained by the applicant from any source (21 CFR 314.50 and 601.2(a)). FDA scientists evaluate this information, and may request additional information as necessary to provide a complete and accurate picture of the product. FDA may supplement the expertise of its in-house scientific personnel with advice from scientific advisory committees of outside experts (21 CFR 14.171).

Under the act and FDA regulations, the agency determines that a drug is approvable based not on an abstract estimation of its safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's benefits and risks under the conditions of use prescribed, recommended, or suggested in the labeling (section 505(d) of the act). FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to use of the product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance. The centerpiece of risk management for prescription drugs generally is the labeling, which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively in accordance with the act.

FDA carefully controls the content of prescription drug labeling, because such labeling is FDA's principal tool for educating health care practitioners about the risks and benefits of the approved product to help ensure safe and effective use. As FDA noted in the preamble accompanying the December 2000 proposed rule amending the 1979 physician labeling regulations:

> The part of a prescription drug product's approved labeling directed to health care practitioners * * * is the primary mechanism through which FDA and drug manufacturers communicate essential, science-based prescribing information to health care professionals. This part of approved labeling is a compilation of information based on a thorough analysis of the new drug application (NDA) or biologics license application (BLA) submitted by the applicant * * * . [T]he primary purpose of prescription drug labeling is to provide practitioners with the essential information they need to prescribe the drug safely and effectively for the care of patients.

(65 FR 81082 at 81082 and 81083). What distinguishes the prescription drug labeling from other information available to practitioners about a prescription drug is that the prescription drug labeling ''is intended to provide physicians with a clear and concise statement of the data and information necessary for the safe and effective use of the drug.'' Moreover, the act ''permits labeling statements with respect to safety only if they are supported by scientific evidence and are not false or misleading in any particular'' (44 FR 37434 at 37435 and 37441).

Under this final rule, risk information must appear in different sections of the prescription drug labeling in a particular order and must be based on data derived from human experience whenever possible. For example, information included in the contraindications section of prescription drug labeling must include only ''[k]nown hazards and not theoretical possibilities'' (§ 201.57(c)(5)). The adverse reactions section must include those adverse events for which there is some basis to believe there is a causal relationship between the event and the drug (§ 201.57(c)(7)).

The act and FDA regulations prescribe several procedures to ensure that FDA receives information about risks that become apparent after approval. Because clinical trials involve time-limited administration of the investigational product to a relatively small and homogeneous population of study subjects, adverse events that were not observed during clinical trials may be recognized or identified following approval. The act provides that a manufacturer must establish and maintain such records, and make such reports, as FDA may require by regulation (section 505(k) of the act). To implement this provision, FDA has issued regulations requiring prompt reports of serious, unexpected drug experiences and periodic reports of all information relating to the safety and effectiveness of the drug (21 CFR 314.80 and 314.81). Manufacturers may also commit to conduct additional safety and effectiveness studies following approval and submit data from these studies to the agency. (See section 506B of the act (21 U.S.C. 356b).)

The statutory and regulatory requirements for the submission of information to FDA are accompanied by statutory provisions addressing the failure of a sponsor to comply with these requirements. A manufacturer that introduces a new drug into interstate commerce without having submitted the required premarket information has violated the act (section 505(a) of the act) and is subject to FDA enforcement action. Similarly, if a manufacturer fails to submit information required by 21 CFR 314.80 and 314.81, it is subject to enforcement action under 21 U.S.C. 331(e). FDA is authorized to investigate suspected fraud using its general statutory investigative authority (section 702 of the act (21 U.S.C. 372)). The agency is also empowered to address fraud by seeking injunctive relief and civil penalties (21 U.S.C. 332, 333(g)(1)(A)), and has authority to invoke the general federal prohibition on making false statements to the Federal Government (18 U.S.C. 1001). In sum, FDA has a variety of enforcement options that allow it to make a calibrated response to suspected violations of the act's information submission requirements.

The agency carefully reviews all the information submitted by a sponsor in a marketing application to make its statutorily required judgment as to whether the product is safe and effective and otherwise in compliance with the act. It also reviews adverse event information submitted after marketing approval and determines what action, if any, should be taken. In rare cases, FDA finds that the information supports a determination to withdraw the product from the market (section 505(e) of the act; 21 CFR 601.5(b)(1)). In other instances, FDA uses other risk management techniques. One such technique is incorporating additional risk information into, or otherwise modifying, the prescription drug labeling (§ 201.57(e)). In many cases, review of the submitted reports does not lead to any change, e.g., because FDA determines that the event reported is not causally related to the product.

Changes to prescription drug labeling typically are initiated by the sponsor, subject to FDA review, but are sometimes initiated by FDA. Under FDA regulations, to change prescription drug labeling (except for editorial and other minor revisions), the sponsor must submit a supplemental application fully explaining the basis for the change (§§ 314.70 and 601.12(f)). FDA permits two kinds of labeling supplements: (1) Prior approval supplements, which require FDA approval before a change is made (§§ 314.70(b) and 601.12(f)(1)), and (2) CBE supplements, which may be implemented before FDA approval, but after FDA notification (§§ 314.70(c) and 601.12(f)(2)). Labeling changes to the FPI to add or strengthen a warning, precaution, contraindication, or adverse reaction statement are within the

category of changes for which CBE supplements are required by FDA regulations (§§ 314.70(c)(6)(iii) and 601.12(f)(2)(i)) (see comment 5). While a sponsor is permitted to add risk information to the FPI without first obtaining FDA approval via a CBE supplement, FDA reviews all such submissions and may later deny approval of the supplement, and the labeling remains subject to enforcement action if the added information makes the labeling false or misleading under section 502(a) of the act. To mitigate this risk, manufacturers often consult with FDA before adding risk information to labeling. As noted in response to comment 5, however, a sponsor may not use a CBE supplement to make most changes to Highlights.

As FDA has long recognized, its role is not to regulate medical practice. The agency's actions nevertheless affect medical practice in a variety of ways. For example, FDA approval decisions affect the availability of drugs and medical devices. Also, FDA decisions as to the content and format of prescription drug labeling affect health care practitioners' communications with patients, to the extent such labeling is relied upon by such practitioners to guide their discussions of risk with patients. FDA strongly believes that health care practitioners should be able to rely on prescription drug labeling for authoritative risk information and that health care practitioners should not be required to convey risk information to patients that is not included in the labeling.

If State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted. Where a drug has not been reviewed by FDA and decisions with respect to safety, effectiveness, and labeling have not been made by the agency, expert determinations would not yet have been made by FDA, and such disruption would not occur.

Section 4(c) of Executive Order 13132 instructs us to restrict any Federal preemption of State law to the ''minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated.'' This final rule meets the preceding requirement because, as discussed in more detail above, it preempts state law only to the extent required to preserve Federal interests. Section 4(d) of Executive Order 13132 states that when an agency foresees the possibility of a conflict between State law and federally protected interests within the agency's area of regulatory responsibility, the agency ''shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict.'' Section 4(e) of Executive Order 13132 adds that, when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency ''shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.''

FDA sought input from all stakeholders on new requirements for the content and format of prescription drug labeling through publication of the proposed rule in the **Federal Register**. Although the proposed rule did not propose to preempt state law, it did solicit comment on product liability issues. FDA received no comments on the proposed rule from State and local governmental entities.

Officials at FDA consulted with a number of organizations representing the interests of state and local governments and officials about the interaction between FDA regulation of prescription drug labeling (including this rule) and state law.

In conclusion, the agency believes that it has complied with all of the applicable requirements under Executive Order 13132 and has determined that this final rule is consistent with the Executive order.

XI. Analysis of Economic Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). Under the Regulatory Flexibility Act, unless the agency certifies that the rule is not expected to have significant economic impact on a substantial number of small entities, an agency must consider alternatives that would minimize any significant impact of the rule on small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

The agency believes that this rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and in these two statutes. The final rule would amend current requirements for the format and content of human prescription drug product labeling. Although the effectiveness of the revised labeling in achieving time savings and reductions in adverse reactions is uncertain, based on the following analysis as summarized in table 9, FDA projects that the present value of the quantifiable benefits of the final rule over 10 years range from $330 million to $380 million and from $420 million to $480 million at a 7 and 3 percent discount rate, respectively. Direct costs of the final rule are projected to range from approximately $7 million to $17 million in any one year, for a total present value of approximately $90 million and $120 million over 10 years at a 7 and 3 percent discount rate, respectively. The agency thus concludes that the benefits of this final rule outweigh the costs. Furthermore, the agency has determined that the final rule is not an economically significant rule as described in the Executive order, because annual impacts on the economy are substantially below $100 million. Because the rule does not impose any mandates on State, local or tribal governments, or the private sector that will result in an expenditure in any one year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates Reform Act. The current inflation-adjusted statutory threshold is about $115 million.

The agency believes that this rule would not have a significant impact on most small entities. However, it is possible that some small firms that produce several affected drugs, or small firms that might be required to undertake packaging modifications, may be significantly affected by this rule. Therefore, the following analysis, in conjunction with the preamble, constitutes the agency's final regulatory flexibility analysis as required by the Regulatory Flexibility Act.

TABLE 9.—SUMMARY OF PROJECTED QUANTIFIABLE BENEFITS AND COSTS OVER 10 YEARS[1]

	Total ($ million)	Present Value ($ million)	
		3 percent	7 percent
Benefits:			
Health Care Practitioner Time Saved	150	120	90
Cost of Adverse Drug Events Avoided	360 to 430	300 to 360	240 to 290
Total Potential Benefits	510 to 580	420 to 480	330 to 380
Costs:			
Design and Produce Trade Labeling; Modify Packaging Equipment	42	36	29
Reformat and Produce Labeling Not Accompanying Drug Products	36	30	25
Print Longer PDR	59	49	39
Total Costs	140	120	90

[1] Numbers may not sum due to rounding.

A. Purpose of the Final Rule

The purpose of the final rule is to make it easier for health care practitioners to find and read information important for the safe and effective use of prescription drugs. As described elsewhere in this preamble, the agency has found that the current format of prescription drug labeling can be improved to more optimally communicate important drug information (see section I of this document). Enhanced communication of drug information to physicians should make them better informed prescribers. The final rule is designed to achieve these objectives by amending the current content and format of the labeling for certain human prescription drug products to, among other things, highlight frequently accessed and new information, include a table of contents for the detailed information in labeling, and reorder this detailed information.

B. Comments on the Economic Impact Analysis

Most comments on the economic analysis of the proposed rule came from pharmaceutical manufacturers. Although many manufacturers expressed concerns that the agency had significantly underestimated the costs to industry, especially the additional packaging costs that would be necessary with labeling printed in 8 points, only a few provided detailed information about the potential burden they expected the rule to impose. The agency welcomes these comments and, whenever possible, has incorporated data from these examples in the final analysis of economic impacts.

(Comment 121) Several comments argued that manufacturers would incur significant administrative costs when negotiating the content of Highlights with FDA.

Although our analysis did not separate administrative costs from other labeling design costs, the agency anticipated that manufacturers would require some ''detailed discussions and drug-specific decisions'' during the design phase of labeling (e.g., regarding exactly which adverse reactions should be listed in Highlights) (65 FR 81082 at 81106). Currently, manufacturers submitting new applications (i.e., NDAs and BLAs) and efficacy supplements have to negotiate the content of labeling as part of the review process. Because any information in Highlights is also in the FPI, the agency does not agree that negotiating the content of Highlights will impose significant administrative costs beyond what is currently incurred by these manufacturers. As noted, to facilitate this process, the agency is making available guidance to assist manufacturers in selecting information for inclusion in Highlights (section IV of this document).

On the other hand, manufacturers of recently approved innovator drugs (i.e., approved within 5 years prior to the effective date of the final rule) will incur costs to: (1) Prepare and submit their redesigned labeling to FDA for approval, which may include negotiations concerning the content of Highlights, and (2) replace existing labeling with redesigned labeling. To account for these additional actions, the one-time design costs for labeling of recently approved products are estimated to be about 50 percent higher than for labeling of new products (see section XI.D.2 of this document).

(Comment 122) The agency sought specific comment on whether the potential impact of the proposed rule on small entities has been accurately estimated by the agency, and whether small business concerns have been adequately addressed. One comment stated that because the proposal has the potential to substantially affect larger companies (could double the length of labeling and require extensive re-engineering and re-design of packaging lines and ancillary equipment), its impact would be even greater on smaller companies.

Although the agency had requested input from small companies that might be affected by the rule, all comments on this question came from large companies. FDA believes it is difficult to predict the effect of the rule on small firms. While small firms may have lower sales volume over which to spread the fixed costs of compliance, some industry consultants have found that small pharmaceutical firms have less organizational layers and incur lower costs for the same activity than large pharmaceutical firms (Ref. 12). Table 22 in section XI.E.2 of this document illustrates the potential impact that the final rule might have on small firms.

(Comment 123) One comment maintained that there is no support for FDA's identified benefit of reducing the time it takes a prescriber to use labeling by 15 seconds. The comment argued that Highlights, because it contains incomplete information, would actually increase physician reading time and asserts that FDA's assumption would be true only if physicians read just Highlights.

The agency acknowledges that there is not direct empirical support for the estimate of 15 seconds time savings, but is persuaded based on consultation with physicians that the labeling changes would save time. The agency consulted physicians in a national survey, focus groups, and a public meeting to design labeling that provides easier and faster access to the most important and commonly referenced prescribing

information (65 FR 81082 at 81083 through 81085; see also Ref. 11). Using a standard format with frequently accessed sections at the beginning of labeling will help physicians find important information quickly and retain that information. Inclusion of Contents and references in Highlights to the full prescribing information that is cited or concisely summarized will speed access to detailed information in the FPI. In the absence of quantitative evidence suggesting a different estimate of time savings, the agency is retaining 15 seconds as a conservative estimate of the amount of time health care practitioners can save when seeking drug product information in labeling.

(Comment 124) Some comments argued that FDA's estimate significantly underestimates increased costs for trade packaging, shipping containers, and new packaging and shipping equipment to accommodate the larger labeling that will result from the new format. Some comments argued that the agency's initial estimate of $200,000 to adjust or retool existing packaging equipment underestimates the impact on industry by almost fourfold. Moreover, one comment stated it could cost large manufacturers with many product lines up to $40 million to change all packaging lines. Several comments stated that increases of this magnitude will require retooling or replacing existing equipment, increasing containers to accommodate longer outserts, or, in some cases, adding a carton. Comments also stated that longer labeling would increase administrative costs.

FDA allows each manufacturer some flexibility to determine the size and shape of a product's trade labeling and packaging. A survey of labeling printed in the Physicians' Desk Reference (PDR) for 200 products showed that, on average, labeling requires 200 square inches of surface area when printed in 6.5-point type size. Since prescription drug labeling is printed on both sides of the paper, these findings suggest that current trade labeling averages 100 square inches. From this baseline, the agency calculates that about an additional 92.6 square inches of paper would be needed to print labeling in 8-point type size and to add Highlights and Contents to the labeling.

To reduce the burden on industry, the final rule requires that trade labeling be printed in at least 6-point type size (see comment 102), similar to the size of the baseline case used in the original analysis and a size generally supported by industry comments on the proposed rule. Even though some trade labeling is currently printed in a size as small as 4 points, on average, trade labeling is in 6 points, and thus requiring a minimum type size of 6-point will not increase the size of most trade labeling. However for the few products currently printed in 4 points, labeling will require approximately 33 percent more paper to conform with the 6-point minimum size requirement at § 201.57(d)(6). The agency believes that the additional resources associated with longer labeling are warranted by the ease of use and speed of comprehension by having labeling printed in 6 rather than 4 points.

Highlights and Contents will increase trade labeling by approximately 40 square inches, requiring an additional 20 square inches of paper. Manufacturers submitting NDAs and BLAs have not yet designed product labeling or packaging. Thus, the agency does not agree that the final rule will impose additional packaging costs on these manufacturers. In contrast, manufacturers submitting efficacy supplements or having existing labeling for drug products affected by the final rule will need to determine if their redesigned trade labeling fits on or within existing packaging.

The final rule will affect less than 15 percent of existing products in the United States.[11] The agency agrees that some packaging lines of these products will require adjustment to accommodate longer trade labeling, but disagrees that this will be necessary for all packaging lines. Based on an analysis of ophthalmic products, the agency increased the proportion of existing products expected to incur one-time production costs from 1 to 5 percent (see section XI.D.2.c.ii of this document).

(Comment 125) One comment insisted that FDA's estimate of 92.6 square inches of additional labeling space is not sufficient to accommodate the proposed new labeling sections, increase in white space, increase in type size, and inclusion of patient information in the FPI. The comment suggested that FDA's presentation of how much additional labeling space would be needed was confusing.

The implementation schedule to add FDA-approved patient labeling to prescription drug labeling differs from the implementation schedule for the formatting and content changes affecting labeling for new and recently approved products (i.e., approved within 5 years of the effective date of the final rule). Consequently, the agency analyzed the impact of each of these requirements separately.

Within 1 year of the effective date of the final rule, any FDA-approved patient labeling must either be reprinted immediately following the end of labeling or accompany the labeling (§§ 201.57(c)(18) and 201.80(f)(2)). An estimated 150-square inches of surface area would be needed to print this information, adding an additional 75-square inches to the size of the labeling (65 FR 81082 at 81109). The agency identified up to 200 products with some form of FDA-approved patient labeling that will be affected by the final rule. A sample of these affected products shows that the labeling of more than 60 percent already conforms to this provision of the final rule. For the final analysis, the agency increased the estimate of the number of affected products from 50 to 80, thus increasing the incremental printing costs for this provision of the final rule to $0.4 million annually (see section XI.D.1 of this document).

More space will be needed to print longer trade labeling and labeling distributed with promotional materials for new and recently approved products. The length will depend on the minimum type size requirements for the labeling. For trade labeling printed in a minimum of 6 points, an estimated 20 square inches of paper is necessary to accommodate Highlights and Contents. In contrast, product labeling distributed with promotional materials must be printed in a minimum 8-point type size, requiring about 93 square inches of paper (65 FR 81082 at 81107). Furthermore, for labeling with FDA-approved patient labeling which is not currently appended to the product labeling, after all provisions of the final rule are implemented, product labeling will be approximately 168 square inches or 65 square inches longer when printed in 8-point or 6-point type, respectively.

(Comment 126) One comment asked the agency to consider the impact of the increased number of calls on companies, and possible increases in personnel to process calls, as a result of requiring companies to include their phone number in the package inserts. Another comment raised concerns that requiring corporate telephone numbers for reporting of serious adverse reactions in Highlights would require companies to change their labeling with each change of their corporate telephone number.

The agency believes that health care practitioners have varied access to company information via the Internet and other sources, thus including the phone number is unlikely to overly burden a company's ability to handle

[11] Data derived from information in "Approved Drug Products with Therapeutic Equivalence Evaluations," December 2001.

incoming calls. The agency believes that changes in corporate phone numbers are an ordinary business expense.

C. Benefits of Regulation

The expected economic benefits of this final rule are the sum of the present values of: (1) The reduced time needed by health care practitioners to seek desired information in prescription drug labeling; (2) the increased effectiveness of drug treatment; and (3) the avoided costs of treating drug-related errors due to misunderstood or incorrectly applied drug information.

We acknowledge that the information to estimate the benefits of this rule is quite limited. In particular, we do not have direct estimates of how much time practitioners might save by using the new labeling, or how the new labeling might improve doctors' understanding of risks of prescription drugs. There is no formal study that tested how alternative labeling formats affect physicians' speed or quality of comprehension of information related to potential adverse effects of drugs.

1. Decreased Health Care Practitioner Time

Prescription drug labeling is a major source of information about the risks and benefits of prescription drugs. Each year health care practitioners spend considerable time seeking medical knowledge about the therapeutic risks and benefits of the drugs prescribed to treat patients. However, only a few studies have focused on the information-seeking behavior of health care practitioners. Four studies using family practice physicians reported that the PDR, a compilation of prescription drug labeling, was the most frequently used reference book in a clinical setting (Refs. 13 through 16). In one study published in 1990, physicians reported using the PDR almost daily (Ref. 13). In addition to the PDR, physicians receive prescription drug labeling directly from drug manufacturers and their representatives.

A 1994 FDA survey of physicians found that 42 percent referred to prescription drug labeling at least once a day, 33 percent less often than once a day but more often than once a week, and 25 percent once a week or less (Ref. 11, pp. 30–31). These findings suggest that a physician seeks drug information from prescription drug labeling on average 212 times each year.[12]

Moreover, comments from a pharmacy association, submitted in response to the proposed rule, reported that a recent informal survey of pharmacists found that 30 percent refer to prescription drug labeling several times each day, 36 percent refer at least once per day, and 34 percent refer at least once per week. If representative, these findings suggest that the average pharmacist in the United States seeks information from prescription drug labeling at least 257 times each year.[13] To put this estimate in perspective, approximately 2.85 billion prescriptions were dispensed by retail pharmacies in 2001 (Ref. 17). About 60 percent of the 212,660 pharmacists in the United States work in retail pharmacies (Refs. 18 and 19) and cumulatively seek information from prescription drug labeling about 32.8 million times each year (212,660 pharmacists x 0.6 x 257 labeling consultations per year), approximately 12 times for every 1,000 prescriptions dispensed.

For the analysis of the proposed rule, FDA was aware of no data estimating the total time physicians spend reading prescription drug labeling. It also had no estimates of how much time savings might result from possible changes in drug labeling. It therefore conservatively assumed that physicians could save an average of 15 seconds each time they refer to prescription drug labeling in the new format (65 FR 81082 at 81104). One comment from a pharmaceutical manufacturing organization requested justification for this assumption (see comment 123). The comment stated that rather than save time, the new format with Highlights would lengthen the time practitioners spend looking for information.

The agency disagrees it will take health care practitioners more time to find information with the new format compared to the old format. As described elsewhere in the preamble, the agency solicited input from health care practitioners to develop a format that presents complex drug information in a manner that will enable them to find information more rapidly, improving the communication of the risks and benefits of the drug (see section I of this document). In comments on the proposed rule, organizations representing health care practitioners and consumer groups strongly supported the new format as being easier and quicker to use (see comment 2). Comments from many drug manufacturers agreed that including a comprehensive table of contents and reordering of the detailed information would improve clarity of the labeling and quickly direct the reader to the appropriate section of the FPI, but expressed reservations about the utility of Highlights (see comment 2).

Comments, including one by an expert in human cognition, supported Highlights as a way to improve the accessibility of the most heavily used information (see comment 2). Moreover, by including references in Highlights to specific sections of the FPI, Highlights will also enhance the effective use of the information in the detailed sections of the labeling. Therefore, based on comments from health care practitioners, professional organizations and consumer groups, the agency believes that the new format will reduce the time physicians, pharmacists, and other practitioners must spend seeking specific information in prescription drug labeling and increase the extent they rely on labeling for drug information.

A recent study in Oregon found that primary care physicians on average will consult two sources of information, one of which is usually the PDR, and spend an average of 12 minutes seeking information to answer patient questions (Ref. 16). Another study in Finland logged the time physicians spent searching a computerized set of guidelines, the ''Physicians' Desk Reference and Database,'' and found the average time needed to find and read an article was 4.9 minutes (Ref. 20).

Although these studies may not be representative of the average practitioner in the United States, they suggest that the agency's estimate of a 15-second time savings with the new format (once drug labeling is at hand) is plausible and conservative in that it is only a small improvement relative to time currently spent for most labeling referrals. If the new format were implemented for all prescription drug products, the nation's 625,100 physicians active in patient care (Ref. 21) could save a total of about 552,100 hours per year (625,100 physicians x 212 labeling consultations per year x 15 seconds saved per labeling consultation/ 3600 seconds per hour). Likewise, pharmacists could save an additional 227,700 hours per year (212,660 pharmacists x 257 labeling consultations per year x 15 seconds saved per labeling consultation/ 3,600 seconds per hour).

The final rule only applies to new and recently approved products. Moreover, implementation for recently approved products is phased in over several years.

[12] On average, physicians work 47 weeks per year and consult prescription drug labeling 4.51 times each week [(7 consultations per week x 42 percent) + (4 consultations per week x 33 percent) + (1 consultation per week x 25 percent)] (65 FR 81082 at 81104 through 81105).

[13] On average, it is assumed that pharmacists work 50 weeks per year and consult labeling 5.14 times per week [(10 consultations per week x 30 percent) + (5 consultations per week x 36 percent) + (1 consultation per week x 34 percent)].

Thus, the final rule will initially apply only to a small percentage of prescription drug labeling. The rule's focus on newer products includes the prescription drug labeling that health care practitioners consult most frequently. In FDA's survey of physicians, newness of the product was the factor most often rated by physicians as ''very likely'' to trigger referral to prescription drug labeling (Ref. 11, p. 35). Similarly, the pharmacy association's survey found that pharmacists were most likely to consult labeling if the drug was recently approved (48 percent).

Although the average practitioner regularly prescribes from 40 to 100 pharmaceutical products (Ref. 24), the proportion of these that are new drugs is unknown. Because the agency received no comments and has no other information on the percentage of reformatted labeling that practitioners will consult, the initial assumptions remain unchanged (65 FR 81082 at 81104). This analysis, therefore, assumes that the rule will begin affecting the length of time needed for prescription drug labeling consultations in the second year of implementation, only affecting 5 percent of all consultations in that year. The percentage of reformatted prescription drug labeling consulted by physicians is assumed to increase to 10, 15, and 25 percent in years 3, 4, and 5 respectively. Thereafter, it is assumed to increase an additional 5 percent each year, reaching 50 percent in year 10. Thus, in year 10, the time savings for physicians and pharmacists is projected to equal about 276,000 and 113,900 hours, respectively. FDA has not attempted to project impacts beyond 10 years, due to the uncertainty of the longer term technological changes that would affect these estimates (see section V of this document).

To estimate the monetary value of the time saved, an hourly loaded wage for physicians is calculated using data from the American Medical Association (AMA) on the average net annual income of all non-Federal physicians (excluding residents), the average weekly workload, average number of weeks worked per year and benefits adjusted by the proportion of self-employed physicians (Refs. 22 and 23). The loaded wage for pharmacists is calculated from Bureau of Labor Statistics data (Ref. 18). At $88.16 per hour for physicians ([$194,400 x (1 + 0.2)] / [47 weeks x 56.3 hours / week]) and $46.75 per hour for pharmacists ($33.39 / hour x (1 + 0.4)), table 10 shows the annual monetary value of time saved and indicates that the present value over 10 years equals approximately $90 million or $120 million using a 7 or 3 percent discount rate, respectively.

TABLE 10.—VALUE OF HEALTH CARE PRACTITIONER TIME SAVED[1]

Year	Current Value ($ million)			Present Value ($ million)	
	Physicians	Pharmacists	Total	Total Discounted at 3 percent	Total Discounted at 7 percent
1	0	0	0	0	0
2	2	1	3	3	3
3	5	1	6	5	5
4	7	2	9	8	7
5	12	3	15	13	11
6	15	3	18	15	12
7	17	4	21	17	13
8	19	4	24	19	14
9	22	5	27	20	15
10	24	5	30	22	15
Total	120	30	150	120	90

[1] Numbers may not sum due to rounding.

2. Improved Effectiveness of Treatment

The final rule will improve prescription drug labeling to make it easier to find and use information about the product. More effective communication of drug information will better inform practitioners about the risks and benefits of drugs prescribed to patients. Prescription drug labeling can contain hundreds of facts about a drug, increasing the time needed to find specific information, relative to simpler labeling. For example, labeling of the drug cisapride contains over 470 facts (Ref. 24). Under the final rule, Highlights would emphasize those characteristics of drugs that physicians report are the most important for decisionmaking. With the Contents and references to the FPI in Highlights, practitioners can more quickly find all relevant facts about the drug that are specific to their patients. Each format change required by the final rule is intended, therefore, to present the complex drug information contained in labeling in a way that will improve the ability of practitioners to select and prescribe drugs to their patients safely and effectively.

The initial U.S. approval date will alert practitioners to newer products that should be used with greater vigilance. There are over 100 NDAs, including about 30 new molecular entities, approved every year in the United States. Initial approval is based on data from clinical trials conducted to determine the safety and effectiveness of a product. These trials typically include only enough subjects to detect 1 adverse reaction in every 300 to 500 patients (Ref. 25). It is not uncommon for drugs to have significant adverse effects that occur at lower frequencies than can be

detected in premarketing clinical trials. Adding contact information where practitioners can report suspected adverse reactions will facilitate the collection of drug safety information and make it easier for the agency and manufacturers to identify significant safety concerns that can emerge after a drug is marketed and a much larger population is exposed to the product. Moreover, by identifying those sections of the labeling in which there have been important recent changes, the new format will also alert practitioners to significant new safety concerns and other significant changes to labeling once a product has been approved.

In addition, any FDA-approved patient labeling must be printed at the end of the labeling, or accompany the labeling, regardless of when the product was approved. Including patient information enhances the likelihood that physicians will communicate important information to patients, improving patient understanding and adherence to treatment recommendations. FDA is unable to quantify the magnitude of these expected improvements in treatment effectiveness and health outcomes, but the agency believes they could be significant.

3. Decrease in Costs to Treat Avoidable Adverse Reactions

Although there are multiple causes of adverse reactions, some are potentially preventable and can result from misunderstood or incorrectly applied drug information (e.g., prescribing too high a dose for a patient with poor kidney function, or prescribing a drug to a patient with known contraindications). According to a 2000 GAO report on adverse drug events, standardized packaging is one of many approaches that can be adopted to reduce medication errors (Ref. 26). Requiring that prescription drug labeling follow a standardized format will better inform health care practitioners about the drugs that are prescribed to patients, improve the effectiveness of treatment, and reduce the number of preventable adverse reactions experienced by patients.

No national study on the incidence or associated costs of adverse reactions has been conducted. Furthermore, it is difficult to compare published studies because they are either too limited in scope or differ in methodology. Nevertheless, studies of hospitalized patients suggest that the rate of preventable adverse events that occur during hospitalization is approximately 1.2 to 1.8 adverse events per 100 patients admitted (Refs. 27 through 29). Moreover, 1 of these studies conducted in the early 1990s in the northeastern United States found that a majority of preventable adverse events (about 1 adverse event per 100 hospital admissions) were related to errors or miscalculations in physician ordering, the stage most likely to be affected by improved prescription drug labeling information (Ref. 28). A more recent study conducted in the southwestern United States reported 4.2 adverse events per 100 patients, of which only 15 percent where deemed preventable (Ref. 29). Given the approximately 36 million annual hospitalizations in the United States (Ref. 30), these data suggest that between 229,000 and 364,000 adverse reactions among hospitalized patients are potentially preventable each year.

A number of studies show that the occurrence of an adverse event in a hospitalized patient increases the costs of caring for the patient by an average of between $2,162 and $2,595 (Refs. 28, 29, and 31). Costs associated with preventable adverse events were even higher, averaging about $4,685 per patient (Ref. 31), or $6,075 in 2000 dollars. If all hospitals incur similar costs for preventable adverse events, the potentially preventable annual costs from this source could total from between $1.4 billion to $2.2 billion nationally (in 2000 dollars).

Few studies on adverse reactions in outpatient or long-term care settings have been conducted. A report from a multidisciplinary conference held in 2000 to discuss a national research agenda for ambulatory patient safety described a diverse and complex outpatient system that was prone to the same types of errors observed in hospital studies (Ref. 32). In 1995, FDA estimated that hospitalizations associated with outpatient adverse reactions cost $4.4 billion per year (60 FR 44182 at 44232; August 24, 1995), equaling $5.2 billion in 2000 dollars. If the causes of errors in the outpatient setting are similar to the causes in hospitals, half of these costs are related to physician ordering errors. Thus, about $2.6 billion (in 2000 dollars) per year in additional hospital costs result from errors likely to be influenced by improved prescribing information.

FDA lacks data to estimate the actual proportion of the adverse reaction costs that would be prevented under the final rule. Combining the projected hospital costs attributable to preventable in-hospital and outpatient adverse reactions, from $4.0 billion to $4.8 billion per year may be potentially avoided through measures that provide better information to doctors, such as prescription drug labeling. If the final rule reduced these costs by even 1 percent, between $40 million and $48 million of the costs of hospitalization could be prevented each year. Over 10 years, the present value of these avoided costs would total from $240 million to $290 million with a 7 percent discount rate, and from $300 to $360 with a 3 percent discount rate (table 11).

Table 11.--Annual Avoided Health Care Costs of Treating Patients for Preventable Adverse Drug Events [1, 2]

Year	Current Value ($ mil)					Present Value ($ mil)			
	Outpatient ADEs	In-Hospital ADEs		Total		Total Discounted at 3 percent		Total Discounted at 7 percent	
		From:	To:	From:	To:	From:	To:	From:	To:
1	0	0	0	0	0	0	0	0	0
2	26	14	22	40	48	38	45	35	42
3	26	14	22	40	48	37	44	33	39
4	26	14	22	40	48	35	43	30	37
5	26	14	22	40	48	34	42	28	34
6	26	14	22	40	48	33	40	27	32
7	26	14	22	40	48	32	39	25	30
8	26	14	22	40	48	32	38	23	28
9	26	14	22	40	48	31	37	22	26
10	26	14	22	40	48	30	36	20	24
Total	230	130	200	360	430	300	360	240	290

[1] Numbers may not sum due to rounding.
[2] Assumes the rule will avoid 1 percent of the preventable hospitalization costs from in-hospital and outpatient adverse drug events.

As illustrated in table 12, the magnitude of the potential benefits of the final rule will be sensitive to the assumed level of effectiveness. At 0.4 percent, the total present value of avoided hospital costs for preventable in-hospital and outpatient adverse drug events will exceed the total present value of the compliance costs for the final rule at both 3 and 7 percent discount rates.

TABLE 12.—IMPACT OF DIFFERENT EFFECTIVENESS LEVELS ON THE TOTAL PRESENT VALUE OF AVOIDED HOSPITAL COSTS TO TREAT PREVENTABLE ADVERSE DRUG EVENTS[1]

Effectiveness Estimate (percent)	Discounted at 3 percent ($ million)		Discounted at 7 percent ($ million)	
	From:	To:	From:	To:
0.1	30	36	24	29
0.4[2]	120	140	97	120
0.5	150	180	120	150
1.0	300	360	240	290
5.0	1,500	1,800	1,200	1,500

[1] Numbers may not sum due to rounding.
[2] Corresponds to the breakeven point where over 10 years, the total present value of hospital costs avoided exceeds the total present value of the compliance costs of the final rule.

When compared with other published studies, the agency's estimate of the cost of adverse reactions is likely less than the total social cost of such events. In particular, FDA's estimates include only hospital costs, and exclude the willingness to pay of patients to reduce these risks. Because these risks include fatality risks, the willingness to pay may be quite large. Using a restrictive definition of adverse events and including direct and indirect costs, a large study of hospital discharge records conducted by Thomas and others in Utah and Colorado was published in 1999 and estimated that preventable adverse events cost society at least $17 billion (in 1996 dollars) each year (Ref. 33). In contrast, a 2001 revision of the 1995 Johnson and Bootman cost-of-illness model used current costs whenever possible and predicted that drug-related illness occurring in ambulatory care settings cost about $177.4 billion each year, or more than 40 times the estimate of avoided costs that was used in the rest of this analysis

(Refs. 34 and 35). While we acknowledge that we have no direct evidence about how the rule would reduce preventable adverse reactions, if the final rule avoided at least one-tenth of a percent of the costs predicted by the Thomas study, annual benefits of the rule would approximately equal annual costs.

D. Costs of Regulation

Except as noted below, the methods used to estimate costs for the proposed rule remain the same for the final impact analysis (65 FR 81082 at 81103 through 81112). When possible, unit costs have been updated.

The proposed rule would have required two broad types of changes to the labeling of prescription drug products. First, labeling of approximately one-third of products already approved for marketing would have been revised to delete or add information within 1 year. Several comments argued that these changes would be quite costly relative to the limited benefits that would be derived and difficult to accomplish in the proposed implementation period (see comment 114). In response to these comments, the agency removed the requirements to delete certain information from all existing prescription drug labeling. Only those products with existing labeling that have FDA-approved patient labeling will be required to revise the labeling within 1 year.

Second, the proposed rule would have revised the content and established format requirements for labeling of new and recently approved applications. Although the agency modified some specific content and format requirements, the staggered implementation schedule and most provisions were retained for the final rule. Therefore, direct costs incurred to change prescription drug labeling include the costs of: (1) Designing or revising prescription drug labeling and submitting the new labeling to FDA, (2) producing longer trade labeling including any equipment adjustments, (3) layout and artwork for labeling not accompanying drug products, (4) producing longer labeling for labeling not accompanying drug products, and (5) printing longer labeling in the PDR.

1. Labeling Changes for All Approved Prescription Drug Products

a. *Affected products*. The agency will require that FDA-approved patient labeling accompany the prescription drug labeling, or be printed following the last section of the prescription drug labeling within 1 year after the effective date of the final rule. The agency identified up to 200 products with some form of FDA-approved patient labeling that will be affected by the final rule. A sample of these affected products shows that the labeling of more than 60 percent already conforms to this provision of the final rule. Therefore, the labeling of an estimated 80 products will need to be revised.

b. *Prescription drug labeling design costs*. On average, prescription drug manufacturers will incur about $2,220 per product in design and implementation costs to append FDA-approved patient labeling to existing prescription drug labeling. Because changes must be made within 1 year of the effective date of the final rule, not all firms will have sufficient time to deplete their inventories of existing prescription drug labeling. With a 12-month implementation period, FDA consultants estimate per product inventory losses of approximately $630. Thus, including excess inventory losses, the cost to change prescription drug labeling is estimated at $2,850 per product (65 FR 81082 at 81109; and 68 FR 6062 at 6074, reflecting updated costs). As shown in table 13, in the first year firms may incur one-time costs of $0.2 million to add FDA-approved patient labeling to the labeling of the affected products.

c. *Incremental printing costs for prescription drug labeling*. Printed patient information would add an estimated 2 pages or about 75-square inches to the length of trade labeling when printed on two sides (65 FR 81082 at 81109). Updating the unit printing costs for inflation, this additional length would increase the incremental printing costs by approximately $6.84 for 1,000 pieces of labeling (75-square inches per piece x $0.0000912 per square inch x 1,000 pieces) (68 FR 6062 at 6074). For the final analysis, FDA estimates that for affected products, up to 650,000 pieces of trade labeling would be distributed each year (section XI.D.2.c.i of this document). For each of the affected products, manufacturers will incur annual incremental costs averaging about $4,440 to print the longer trade labeling (650,000 pieces per product per year x $6.84 per 1,000 pieces). For all 80 affected products, annual incremental printing costs for trade labeling will increase by $0.4 million. Furthermore, manufacturers distributing longer prescription drug labeling with promotional materials and samples will spend up to an additional $5,125 in annual incremental printing costs each year for 3 years (750,000 pieces per year x $6.84 per 1,000 pieces (approximation based on information in footnote 17 in section XI.D.2.e of this document)). Therefore, industry will incur additional printing costs with a present value of approximately $3.6 million or $4.2 million over 10 years at a 7 or 3 percent discount rate, respectively (table 13).

d. *Physicians' Desk Reference (PDR) Costs*. The agency estimates that 75 percent of prescription drug products have labeling already printed in the PDR. In 2002, an additional page in the PDR costs manufacturers $9,750.[14] Thus, the per product annual cost to print two additional pages is about $19,500 ($9,750 x 2). For the estimated 60 affected products (80 products x 0.75), the annual PDR costs would increase by $1.2 million ($19,500 x 60), equaling a present value of approximately $8.2 million or $10.0 million over 10 years with a 7 or 3-percent discount rate, respectively (table 13).

TABLE 13.—COSTS TO INCLUDE FDA-APPROVED PATIENT LABELING WITH LABELING OF EXISTING PRESCRIPTION PRODUCTS[1, 2]

Year	One-Time Labeling Revision Costs ($ million)	Annual Incremental Printing Costs ($ million)	Annual PDR Costs ($ million)	Total Costs ($ million)
1	0.2	0.8	1.2	2.2
2	0.0	0.8	1.2	1.9

[14] Not all of these costs to manufacturers are social costs, as the PDR publisher is presumably selling additional pages at more than its true opportunity cost. The excess is a transfer, but we do not know its magnitude.

TABLE 13.—COSTS TO INCLUDE FDA-APPROVED PATIENT LABELING WITH LABELING OF EXISTING PRESCRIPTION PRODUCTS[1, 2]—Continued

Year	One-Time Labeling Revision Costs ($ million)	Annual Incremental Printing Costs ($ million)	Annual PDR Costs ($ million)	Total Costs ($ million)
3	0.0	0.8	1.2	1.9
4	0.0	0.4	1.2	1.5
5	0.0	0.4	1.2	1.5
6	0.0	0.4	1.2	1.5
7	0.0	0.4	1.2	1.5
8	0.0	0.4	1.2	1.5
9	0.0	0.4	1.2	1.5
10	0.0	0.4	1.2	1.5
Total Cost	0.2	4.8	11.7	16.7
Present Value of Total Discounted at 3 percent	0.2	4.2	10.0	14.4
Present Value of Total Discounted at 7 percent	0.2	3.6	8.2	12.0

[1] Numbers may not sum due to rounding.
[2] This estimate assumes that products with Medication Guides already conform to this requirement of the final rule.

2. Labeling Changes for New and Recently Approved Prescription Drug Products

a. *Affected products*. The final rule would require that prescription drug labeling conform to format and content requirements for three categories of products: (1) All NDAs, BLAs, and efficacy supplements submitted to FDA on or after the effective date, (2) NDAs, BLAs, and efficacy supplements approved over the 5 years preceding the effective date or pending on the effective date of the final rule, and (3) any ANDA that references a listed drug with labeling conforming to the requirements of the final rule. For the first category of products, the prescription drug labeling requirements would apply when a sponsor files an NDA, BLA or efficacy supplement. Products in the second category must file supplemental applications within 3 to 7 years of the issuance of the rule, according to the implementation plan described in the preamble (see Table 5). For ANDA products (generic products), the implementation schedule for the affected reference listed drug applies. This rule does not cover labeling for OTC products (including those approved under an NDA).

Estimates of the number of new applications that would be affected by the rule are updated and based on application approvals since 1997. During this period, an average of 97 NDAs and 10 BLAs were approved each year. FDA assumes that this average rate will continue. The number of affected products approved within 5 years before the effective date are estimated as the number of NDAs approved during the 5-year period from 1997 through 2001 without subsequent efficacy supplements.

Most efficacy supplements are filed and approved within 5 years of the approval date of their original application. Over time, prescription drug labeling of most products affected by the final rule will already conform to the requirements of the final rule when an efficacy supplement is submitted. Beginning in year 3, therefore, the number of labeling revisions as a result of an efficacy supplement will decline over time.

The initial analysis of impacts did not include estimates of the number of generic products that would be affected because the period of exclusivity for most innovator products covered by the rule would extend beyond the 10-year horizon. However, a subsequent analysis of data from ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book) found that some older innovator products with generic equivalents have recent approvals of efficacy supplements or NDAs for new dosage strengths that could trigger revision of the labeling of some reference listed drugs. Although the overall number of older innovator products affected by the final rule is anticipated to be small, normally there are multiple generic products for each reference listed drug. Therefore, beginning in year 3, the final rule is estimated to affect an average of 42 generic products annually. Table 14 shows the number of products projected to be affected by the final rule during the 10-year period following the effective date.

TABLE 14.—ESTIMATED NUMBER OF AFFECTED PRODUCTS BY APPLICATION TYPE

Year	New NDAs and BLAs	Efficacy Supplements	Approvals 5 Years Prior to Effective Date	ANDAs	Total
1	107	69	0	0	176

TABLE 14.—ESTIMATED NUMBER OF AFFECTED PRODUCTS BY APPLICATION TYPE—Continued

Year	New NDAs and BLAs	Efficacy Supplements	Approvals 5 Years Prior to Effective Date	ANDAs	Total
2	107	69	0	0	176
3	107	52	69	42	270
4	107	39	69	42	257
5	107	29	68	42	246
6	107	22	69	42	240
7	107	16	69	42	234
8	107	12	0	42	161
9	107	9	0	42	158
10	107	7	0	42	156
Total	1,070	324	344	336	2,074

b. *Prescription drug labeling design costs*. The cost of designing prescription drug labeling that conforms to the final format and content requirements will depend heavily on when, during a product's life cycle, labeling design occurs. Costs will be highest for products already marketed with approved prescription drug labeling that otherwise would not be changed. Conversely, design costs will be lowest for products that are closely related to a prior product application that has already had its prescription drug labeling changed to the new format or for generic drug labeling. Costs for currently marketed products that would be undergoing relabeling for other reasons (e.g., related to an efficacy supplement) will be in between these extremes.

FDA has previously estimated that it takes about 2 months of full-time effort to design a novel patient information guide (for the first prescription drug in a therapeutic class), but less than 1 week to redesign a guide following a previously approved prototype (i.e., innovator drugs in the same therapeutic class for which patient information was already developed) (60 FR 44232). The final rule requires reordering of the detailed information in the prescription drug labeling and addition of Highlights and Contents. Although FDA designates the new order, detailed discussion and drug-specific decisions (e.g., regarding exactly what should be listed in Highlights) may be necessary. Because negotiation of labeling is a routine part of the review process, including Highlights and Contents does not increase this time burden on manufacturers or the agency. Therefore, the time required to revise labeling conforming to the requirements of the final rule will fall between the time required to design a novel patient information guide and time required to redesign a guide. Although sponsors of new applications and efficacy supplements would incur many of the same design costs as sponsors of existing innovator products, they would experience no additional testing, preparation, and application costs. For the initial analysis, it was anticipated that manufacturers would incur one-time costs up to $5,000 for each new product and $7,500 for each existing product to conform to the format and content provisions of the rule (65 FR 81082 at 81106 through 81107). These one-time per product costs are updated to $6,190 and $8,700, respectively. Modifying prescription drug labeling for ANDAs is anticipated to cost generic drug manufacturers about $1,300 per product, including $830 in labor costs and $470 in material costs for artwork and scrap (68 FR 6062 at 6074).

Once product labeling contains Highlights, any substantive revisions of key sections of the labeling must be listed in the recent major changes section along with the month and year the revision was incorporated. However, the final rule also requires that after 1 year, the information about recent major changes must be removed the next time the labeling is reprinted. Manufacturers voluntarily change drug product labeling frequently during the first 5 years a product is marketed. During this period, the agency anticipates that manufacturers would remove recent major changes from Highlights at the same time they voluntarily change labeling and, thus, would incur no additional costs. After 5 years on the market, however, some manufacturers would incur additional costs to remove recent major changes in the timeframe specified by the final rule. The earliest this might occur is in year 7 after the initial redesign of the labeling.[15] Based on the agency's experience with products that have been on the market for more than 5 years, up to 10 percent of the products affected by the final rule might be required to remove recent major changes in year 7 or later, at a per product cost of approximately $1,600. Over 10 years, the present value of these costs could equal about $0.1 million with either a 7 percent or 3 percent discount rate.

As shown in table 15, the total first-year costs would amount to $1.1 million. Costs increase to a high of $1.6 million in years 3 and 4. After the seventh year, when all products approved within 5 years prior to the rule's effective date or pending on the effective date have redesigned prescription drug labeling, the costs decline to about $0.8 million per year. As a result, the estimated total present value of the costs of redesigning prescription drug labeling over 10 years is about $8.8 million and $10.5 million with a 7 and 3 percent discount rate, respectively.

[15] Recent major changes must remain in the Highlights for at least 1 year. Any major change after year 5 would therefore remain on the labeling through year 6 or later.

TABLE 15.—ESTIMATED PRESCRIPTION DRUG LABELING DESIGN COSTS[1]

Year	Current Value ($ million)					Present Value ($ million)	
	NDAs and BLAs	Efficacy Supplements	Approvals 5 Years Prior to Effective Date	ANDAs	Total	Total Discounted at 3 percent	Total Discounted at 7 percent
1	0.7	0.4	0.0	0.0	1.1	1.1	1.0
2	0.7	0.4	0.0	0.0	1.1	1.0	1.0
3	0.7	0.3	0.6	0.1	1.6	1.5	1.3
4	0.7	0.2	0.6	0.1	1.6	1.4	1.2
5	0.7	0.2	0.6	0.1	1.5	1.3	1.1
6	0.7	0.1	0.6	0.1	1.5	1.2	1.0
7	0.7	0.1	0.6	0.1	1.5	1.2	0.9
8	0.7	0.1	0.0	0.1	0.8	0.7	0.5
9	0.7	0.1	0.0	0.1	0.8	0.6	0.4
10	0.7	0.0	0.0	0.1	0.8	0.6	0.4
Total	6.7	2.0	3.0	0.4	12.2	10.5	8.8

[1] Numbers may not sum due to rounding.

c. *Costs associated with producing longer labeling accompanying drug products and drug samples (trade labeling).* The proposed rule would have required that trade labeling be printed in 8-point minimum type size, almost doubling the current average length for the labeling. Several comments from pharmaceutical manufacturers stated that the agency had underestimated the retooling and packaging line costs that would be incurred to include this longer trade labeling (see comment 124). A few large firms estimated that new equipment would cost between $135,000 and $700,000 per packaging line and could total up to $40 million for a large firm if trade labeling of all products were affected. As discussed in section XI.F of this document (''Alternatives Considered''), the agency recognized that including all products in the final rule would substantially increase costs to industry and, therefore, limited the final rule to new and recently approved products (see section XI.F.3 of this document). Furthermore, approximately half of the affected products shown in table 14 will be new approvals that have not yet established packaging. Nevertheless, based on the potential economic impact the larger type size might have on pharmaceutical manufacturers, for the final rule the agency reduced the minimum size requirement for trade labeling to 6 points, a size generally reported as acceptable in comments from manufacturers (see comment 102). Thus, the new format and content requirements of the final rule will lengthen trade labeling by approximately 20 square inches when printed on two sides. Longer prescription drug labeling increases the cost of paper, ink, and other ongoing incremental printing costs. As discussed below, even in 6 points, a small number of products are still expected to incur some equipment costs (e.g., different insert-folding machinery).

i. *Incremental printing costs for trade labeling.* U.S. retail pharmacies dispense about 3.3 billion prescriptions per year, of which an estimated 790 million are for unit-of-use products that include prescription drug labeling within the package (65 FR 81082 at 81107, updated using IMS data at *http://www.ims-health.com*). If the non-unit-of-use prescriptions average one piece of labeling per 3.3 prescriptions, the total number of labelings accompanying retail products equals roughly 1.5 billion. Further, adding hospital pharmaceutical volume, estimated at approximately 54 percent of retail volume, yields an annual total of 2.4 billion pieces of trade labeling accompanying prescribed products. Allowing 10 percent for wastage indicates that manufacturers distribute roughly 2.6 billion pieces of labeling with prescribed products each year. Since 60 percent of all prescriptions are for branded products, about 1.6 billion pieces of labeling are currently included with about 2,440 branded products and about 1.0 billion pieces are included with 2,900 generic products.[16] Using 650,000 pieces per innovator product and 370,000 pieces per generic product, at a cost of $0.18 and $0.19 per 100 pieces, respectively, yields annual per product cost estimates of $1,165 and $700, respectively. Table 16 shows the estimated number of revised labelings and annual incremental printing costs over 10 years.

Trade labeling must also accompany drug product samples. However, the number of samples distributed for a specific product depends on a manufacturer's marketing strategy and may vary from year to year. Although IMS Health (IMS) reported that the volume of samples distributed in the United States between 1997 and 2000 ranged from 860 million to 920 million (Ref. 36), sales representatives normally leave one piece of labeling for every 10 samples they distribute. Even though new products are sampled more often than older products, some manufacturers continue to distribute samples throughout the life cycle of their product. While the actual number of samples including reformatted trade labeling is uncertain, we anticipate that manufacturers may spend up to $0.2

[16] Derived from ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' CDER, FDA, 2001. The estimate is a count of all branded products marketed under an NDA and differentiated by active ingredient, therapeutic equivalence, dosage form, or manufacturer, not including multiple dosage strengths. Although not counted, adding biologicals would not significantly alter results.

million annually to print longer trade labeling to accompany drug samples (table 16).

Table 16.--Incremental Annual Printing Costs for Longer Trade Labeling in 6-Point Minimum Type Size[1]

Year	Number by Type (million)			Current Value ($ mil)				Present Value ($ mil)	
	NDA, BLA, and ES	ANDA	Samples	NDA, BLA, and ES	ANDA	Samples	Total	Total Discounted at 3 Percent	Total Discounted at 7 Percent
1	110	0	90	0.2	0.0	0.2	0.4	0.4	0.3
2	230	0	90	0.4	0.0	0.2	0.6	0.5	0.5
3	380	16	90	0.7	0.0	0.2	0.9	0.8	0.7
4	520	31	90	0.9	0.1	0.2	1.1	1.0	0.9
5	650	47	90	1.2	0.1	0.2	1.4	1.2	1.0
6	780	62	90	1.4	0.1	0.2	1.7	1.4	1.1
7	900	78	90	1.6	0.1	0.2	1.9	1.6	1.2
8	980	93	90	1.8	0.2	0.2	2.1	1.7	1.2
9	1,100	110	90	1.9	0.2	0.2	2.3	1.7	1.2
10	1,100	120	90	2.0	0.2	0.2	2.4	1.8	1.2
Total	6,750	560	900	12.1	1.1	1.6	14.7	12.1	9.4

[1] Numbers may not sum due to rounding.

ii. *Equipment costs.* The original analysis estimated that 1 percent of affected existing products would be required to adjust packaging equipment with trade labeling printed in 8 points. According to several comments, trade labeling is currently printed in type sizes of 4.5 points and larger (see comment 102). Thus, it is unlikely that the minimum type size requirement of the final rule (i.e., 6 points for trade labeling) will require firms to purchase new packaging equipment. However, in a few cases where existing labeling is printed in type sizes between 4.5 points and 6 points, firms may need to adjust packaging lines for longer labeling. Since the labeling of many ophthalmic drug products is printed in type sizes smaller than 6 points, the proportion of recent approvals for ophthalmic products was used as a proxy for the proportion of affected products that will incur some equipment costs. For the final analysis, 5 percent of existing products affected by the rule (i.e., products with new efficacy supplements, products approved in the 5 years prior to the effective date of the rule, and affected ANDAs) will incur costs of $200,000 each product. As shown in table 17, the estimated present value of equipment changes totals $7.2 million and $8.7 million over 10 years discounted at 7 and 3 percent respectively.

TABLE 17.—COST OF ADJUSTMENTS TO PACKAGING LINES TO ACCOMMODATE LONGER TRADE LABELING[1, 2]

Year	Estimated Number of Affected Products	Total Cost ($ million)	Present Value ($ million)	
			Total Discounted at 3 Percent	Total Discounted at 7 Percent
1	3	0.7	0.7	0.6
2	3	0.7	0.7	0.6
3	8	1.6	1.5	1.3
4	8	1.5	1.3	1.1
5	7	1.4	1.2	1.0
6	7	1.3	1.1	0.9
7	6	1.3	1.0	0.8
8	3	0.5	0.4	0.3
9	3	0.5	0.4	0.3
10	2	0.5	0.4	0.2

TABLE 17.—COST OF ADJUSTMENTS TO PACKAGING LINES TO ACCOMMODATE LONGER TRADE LABELING[1, 2]—Continued

Year	Estimated Number of Affected Products	Total Cost ($ million)	Present Value ($ million)	
			Total Discounted at 3 Percent	Total Discounted at 7 Percent
Total	50	10.0	8.7	7.2

[1] Numbers may not sum due to rounding.
[2] For products with labeling printed in type sizes smaller than 6 points, the final rule may require that some packaging lines be retooled. Based on NDA, ANDA or efficacy supplements approvals for ophthalmic drug products between 1997 and 2001, an estimated 5 percent of the existing products affected by the rule will require some change to packaging equipment at an average cost of $200,000 per product.

d. *Layout and design costs for prescription drug labeling not accompanying drug products.* The final rule specifies a minimum type size of 6 points for trade labeling and 8 points for all other prescription drug labeling distributed by a manufacturer (e.g., labeling required to be distributed with promotional materials or in promotional settings). Firms choosing to print all prescription drug labeling for a product in the same type size (8 points or larger) will incur no additional design costs. However, if trade labeling is printed in a type size smaller than 8 points, a firm will incur additional costs of $810 per product to change and proof read the layout, and to prepare artwork for the labeling not accompanying the drug product. It is uncertain how many firms will print labeling in different type sizes. However, if all new and recently approved innovator products are affected, the total present value of the additional design costs is approximately $1.0 million or $1.2 million over 10 years discounted at 7 or 3 percent respectively (table 18).

TABLE 18.—ESTIMATED ONE-TIME LAYOUT AND DESIGN COSTS FOR LABELING NOT ACCOMPANYING DRUG PRODUCTS[1,2]

Year	Number of Affected Products	Total Costs ($ million)	Present Value ($ million)	
			Total Discounted at 3 Percent	Total Discounted at 7 Percent
1	176	0.1	0.1	0.1
2	176	0.1	0.1	0.1
3	228	0.2	0.2	0.2
4	215	0.2	0.2	0.1
5	204	0.2	0.1	0.1
6	198	0.2	0.1	0.1
7	192	0.2	0.1	0.1
8	119	0.1	0.1	0.1
9	116	0.1	0.1	0.1
10	114	0.1	0.1	0.0
Total	1,738	1.4	1.2	1.0

[1] Firms are expected to only print this type of labeling for 3 years after the launch of a new innovator drug product.
[2] Numbers may not sum due to rounding.

e. *Costs associated with producing longer prescription drug labeling not accompanying drug products.* In contrast to trade labeling, with the new content and format requirements the length of current labeling will increase an average of about 93 percent when printed in 8-point type size. At this length, the incremental printing costs will increase by $0.85 per 100 pieces. To calculate the annual cost to print prescription drug labeling not accompanying drug products, FDA estimated that pharmaceutical representatives detailing drug products would distribute approximately 50 million pieces of prescription drug labeling annually. Because most detailing involves relatively new products, the products most affected by this rule, FDA assumed that manufacturers would incur additional printing costs for all of this labeling, amounting to about $0.4 million annually.

Finally, FDA estimated that about 730,000 pieces of prescription drug labeling per approval would be distributed each year by mail or at conferences to physicians, other health care practitioners, consumers, retail pharmacy outlets, and hospital pharmacies for 3 years following approval of a new drug.[17] As shown in table 19, annual total costs peak at $4.4 million in year 5. Over 10 years with a 7 or 3 percent discount rate, the present value of the incremental printing costs

[17] For each approval, it was assumed that all physicians involved in primary care and 25 percent of physicians practicing a medical specialty would receive two mailings per year, or an estimated 646,150 pieces (i.e., (222,400 x 2) + (0.25 x 402,700 x 2)), for 3 years following product launch. An additional 10 percent or 64,615 pieces are estimated to be distributed annually for 3 years to other health care practitioners or consumers. Furthermore, FDA assumes that 55,581 retail pharmacy outlets and 8,020 hospital pharmacies would receive 1 mailing to announce the launch of a new innovator product in the year of approval (65 FR 81082 at 81108, updated).

for longer prescription drug labeling not accompanying drug products would be about $24 million or $29 million, respectively.

Table 19.--Annual Incremental Printing Costs for Longer Prescription Drug Labeling Not Accompanying Drug Products Printed in 8-Point Minimum Type Size[1]

Year	Number of Affected Innovator Products	Number of Pieces and Type of Delivery (million)		Current Value of Costs ($ mil)			Present Value ($ mil)	
		In-Person	Mailed	In-Person	Mailed	Total Cost	Total Discounted at 3 Percent	Total Discounted at 7 Percent
1	176	50	140	0.4	1.2	1.6	1.5	1.5
2	176	50	260	0.4	2.2	2.6	2.5	2.3
3	228	50	430	0.4	3.6	4.0	3.7	3.3
4	215	50	450	0.4	3.8	4.3	3.8	3.3
5	204	50	470	0.4	4.0	4.4	3.8	3.2
6	198	50	450	0.4	3.8	4.2	3.6	2.8
7	192	50	430	0.4	3.7	4.1	3.3	2.6
8	119	50	370	0.4	3.1	3.6	2.8	2.1
9	116	50	310	0.4	2.6	3.1	2.3	1.7
10	114	50	260	0.4	2.2	2.6	1.9	1.3
Total	1,738	500	3,600	4.0	30.2	34.5	29.3	23.9

[1] Numbers may not sum due to rounding.

f. *Physicians' Desk Reference (PDR) Costs.* FDA estimates that the new Highlights, including any boxed warnings, and Contents would add about a half page to the PDR labeling of each affected prescription drug product. Based on conversations with Medical Economics (the publisher of the PDR) on the cost per printed page, FDA estimates that the annual publishing costs of the extra space required for printing the expanded prescription drug labeling would be about $5,550 for each affected product, plus an additional cost if the product was included in one of two annual supplements. FDA assumed that these costs would be incurred by the pharmaceutical industry via publishing fees paid to Medical Economics. The agency assumed that 75 percent of the new drugs and efficacy supplements would be published in the PDR (some smaller firms decline to publish labeling in the PDR). FDA also assumed that 90 percent of the new drugs published would be included in the PDR supplements and 33 percent of the published efficacy supplements would be included in the PDR supplements (about half are actually included, but only two-thirds of these include full prescription drug labeling; the remainder include only the added indication). FDA also assumed that the prescription drug labeling changes made as a result of the 5-year rule (applications approved in the 5 years preceding the effective date of the final rule) would not be included in the PDR supplements. Based on these assumptions, the estimated cost of publishing the extended prescription drug labeling in the PDR would be about $1.2 million for year 1. These costs would continue to increase over time as all drug approvals after the effective date of the rule would have longer PDR listings. The estimated annual and total costs of printing longer PDR listings are shown in table 20.

TABLE 20.—COST TO PRINT LONGER LISTINGS IN THE PDR[1, 2]

Year	Current Value ($ million)			Present Value ($ million)	
	PDR Bound	PDR Supplement	Total Costs	Total Discounted at 3 Percent	Total Discounted at 7 Percent
1	0.7	0.5	1.2	1.2	1.1
2	1.5	0.5	2.0	1.8	1.7
3	2.4	0.5	2.9	2.6	2.4

TABLE 20.—COST TO PRINT LONGER LISTINGS IN THE PDR[1, 2]—Continued

Year	Current Value ($ million)			Present Value ($ million)	
	PDR Bound	PDR Supplement	Total Costs	Total Discounted at 3 Percent	Total Discounted at 7 Percent
4	3.3	0.5	3.8	3.3	2.9
5	4.2	0.4	4.6	4.0	3.3
6	5.0	0.4	5.4	4.5	3.6
7	5.8	0.4	6.2	5.0	3.9
8	6.3	0.4	6.7	5.3	3.9
9	6.8	0.4	7.2	5.5	3.9
10	7.2	0.4	7.6	5.7	3.9
Total	43.1	4.5	47.6	39.1	30.5

[1] Numbers may not sum due to rounding.
[2] Printed in 6.5-point type size at an average per page cost of $9,755.

Table 21 summarizes the estimated compliance costs for the three major cost categories over a 10-year period.

TABLE 21.—COMPLIANCE COSTS OVER 10-YEAR PERIOD[1]

Year	Cost Category ($ million)			Total Costs ($ million)
	Design and Producing Trade Labeling; Modify Packaging Equipment	Reformat and Producing Labeling Not Accompanying Drug Products	Printing PDR	
1	3.1	1.7	2.4	7.3
2	3.1	2.8	3.1	9.0
3	4.9	4.2	4.1	13.2
4	4.6	4.4	4.9	13.9
5	4.6	4.6	5.8	15.0
6	4.8	4.4	6.6	15.8
7	5.0	4.3	7.4	16.6
8	3.8	3.6	7.9	15.3
9	4.0	3.1	8.3	15.5
10	4.0	2.7	8.8	15.5
Total Current Value	42.0	35.9	59.3	137.2
Total Present Value Discounted at 3 Percent	35.7	30.5	49.0	115.3
Total Present Value Discounted at 7 Percent	29.2	24.9	38.8	92.9

[1] Numbers may not sum due to rounding.

E. Impacts on Small Entities

1. The Need for and the Objective of the Rule

Developments in recent years have contributed to an increase in the length and complexity of prescription drug labeling, making it more difficult for health care practitioners to quickly find specific information about a drug. Therefore, practitioners expend time that could be spent with patients and may miss critical information about the safe and effective use of prescription drug products. The objective of the requirements is to improve prescription drug labeling by making it easier for health care practitioners to access, read, and use labeling information about prescription drug products. The agency believes that having better access to critical information will improve the use of prescription drugs and lead to a decrease in the number of preventable adverse reactions that occur in the United States each year.

2. Description and Estimate of the Number of Small Entities Affected

This final rule would affect all small entities required to design their prescription drug labeling to comply with this rule. The Small Business Administration (SBA) considers Pharmaceutical Preparation Manufacturing firms (NAICS 325412) and Biological Product Manufacturing firms (NAICS 325414) with fewer than 750 and 500 employees, respectively, to be small. U.S. Census reports in 1999 there were 265 biological product manufacturing firms (Ref. 37) and 749 pharmaceutical preparation manufacturing firms (Ref. 38). However, employment size classes for pharmaceutical preparation manufacturing do not correspond to SBA size categories. Nevertheless, 1999 Census data suggest that approximately 94 percent of biological product manufacturing firms and at least 87 percent of the pharmaceutical preparation manufacturing firms could be considered small. Despite the large number of small manufacturers, large companies manufacture most prescription drug products. Although the agency cannot predict the number of new approvals granted to small entities, the following estimates are based on 5 years of recent submissions (65 FR 81082 at 81110, updated for 1997–2001). On average, 17 small entities will receive product approvals each year. In addition, about 64 small entities will be affected during years 3 to 7 of the rule, when applicants with products approved 5 years prior to the effective date of the final rule must submit reformatted prescription drug labeling for approval. Only six firms will have more than two existing products affected by the rule. Of these six, four firms will have two products affected in the same year and one firm will have three products affected in a single year.

The compliance requirements for small entities under this final rule are the same as those described above for other affected entities. Compliance primarily involves: (1) designing prescription drug labeling that conforms to the content and format requirements, and (2) once the labeling is approved by FDA, ensuring that all future printed prescription drug labeling is in the new format with the required minimum type size. Because manufacturers already submit labeling with NDAs, BLAs and efficacy supplements to FDA, no additional skills will be required to comply with the final rule.

The group of small entities likely to bear the highest total costs under this final rule are those firms that have: (1) Existing products with prescription drug labeling that must be revised in the first year or (2) more than one affected high-volume product per year, such as a small firm with two or three recently approved, high-volume products that must undergo prescription drug labeling reformatting simultaneously in the same year. However, the high-cost small entities are also the small firms with the highest sales of affected product; thus, their incremental cost per unit sold is likely to be relatively low. In contrast, small firms with a single, low-volume product would have lower costs of compliance, but the incremental cost per unit sold would be higher.

Although the agency solicited comment on the initial regulatory flexibility analysis from small entities, the only comments submitted specifically about the impact on small entities were from large firms (see comment 122). The following examples illustrate possible impacts on small entities with different production volumes. Prescription drug labeling costs are estimated for a small firm with a single carton-enclosed product (marketed under an NDA) that must: (1) Have its labeling reformatted in year 3 of the rule and (2) add patient information in year 1. Table 22 outlines the projected per-unit and total costs to the firm with 3 different levels of production: 1,000, 10,000, and 100,000 units produced per year.

In addition to the costs identified in table 22, a very small number of small firms might incur equipment costs to include longer prescription drug labeling in carton-enclosed products. It is likely, however, that this one-time capital cost (estimated at $200,000) will affect a total of no more than two or three small firms in the 10 years following implementation of the rule. Based on this analysis, FDA believes that the final rule would not have a significant impact on most small entities in this industry, but it is possible that a few small firms may be significantly affected by the final rule.

TABLE 22.—ESTIMATED COSTS FOR HYPOTHETICAL SMALL FIRM WITH A SINGLE PRODUCT, UNDER THREE ALTERNATIVE LEVELS OF PRODUCTION[1]

Cost Category	Number of Units Produced and Sold Each Year		
	100,000	10,000	1,000
Example 1—Revise labeling of product approved less than 1 year prior to effective date:			
Prescription drug labeling redesign/application	$8,700	$8,700	$8,700
Printing trade labeling[2]	$200	$20	$2
Printing prescription drug labeling not accompanying drug products[3]	$1,050	$105	$10
Total	$9,950	$8,825	$8,712
Additional cost per unit sold	$0.10	$0.88	$8.71
Example 2—Add printed patient information to existing labeling for a product:			
Prescription drug labeling redesign	$2,850	$2,850	$2,850
Printing trade labeling[4]	$750	$75	$8
Printing longer PDR[5]	$19,500	$19,500	N/A
Total	$23,100	$22,425	$2,858
Additional cost per unit sold	$0.23	$2.24	$2.86

[1] Numbers may not sum due to rounding.

[2] Number of pieces of trade labeling printed is calculated as units produced/year plus 10 percent wastage factor, at an incremental printing cost of $0.001791 per labeling.

[3] To calculate the cost for printing labeling not accompanying drug products, the number of units is adjusted by the ratio of the average number of pieces printed for mailings to the average number printed as trade labeling (i.e., 1.126), and multiplied by the incremental printing cost of $0.0085 per piece.

[4] Number of pieces of trade labeling printed is calculated as units produced/year plus 10 percent wastage factor, at an incremental printing cost of $0.006837 per labeling.

[5] Assume that prescription drug labeling is already being printed in the PDR. Most low-volume products (i.e., less than 10,000 units per year) will not have labeling in the PDR.

F. Alternatives Considered

1. Do Nothing

The agency considered and rejected this option. The current prescription drug labeling is complex, requiring health care practitioners to spend unnecessary time seeking information they need for the safe and effective use of drug products by their patients. Preventable adverse reactions have many causes and are a serious public health issue. Changing prescription drug labeling to meet the needs of health care practitioners that use it is one of many public health initiatives aimed at reducing these adverse reactions and improving health care.

2. Formatting Alternatives

FDA has considered numerous alternative formats, including a longer Highlights. Highlights is limited to one-half page in 8 points to respond to health care practitioners' concerns about length as well as to reduce the incremental printing costs to manufacturers.

The agency also considered requiring larger minimum type sizes. A 10-point minimum size requirement would increase the amount of paper needed to print the average reformatted labeling by about 200-square inches at an incremental cost of $18,000 per million pieces. Over 10 years, the total present value of producing longer trade labeling in 10 points compared to 6 points would equal $95 million or $120 million with a 7- or 3-percent discount rate, respectively. In addition to higher incremental printing costs, requiring 10-point minimum type size would make labeling so large that many manufacturers would be forced to modify or replace packaging equipment. The agency therefore rejected this option because the potential benefits of the larger type size did not outweigh the costs.

The agency also considered and rejected a 10-point minimum size requirement for labeling not accompanying drug products. Compared to the minimum requirement of 8 points in the final rule, this larger type size would have taken about 100-square inches more paper at an incremental cost of $9,000 per million pieces.

Finally, the agency proposed a minimum size requirement of 8 points for trade labeling instead of the 6-point requirement in the final rule. At 6 points, the average revised labeling will increase by about 20-square inches. Requiring the larger minimum size would take another 70-square inches of paper and cost industry about $6,000 per million pieces of trade labeling. Because this requirement would be burdensome on industry, the agency rejected the 8-point minimum type size.

3. Alternative Categories of Affected Products

Three alternative categories of products to be covered by the rule were considered: (1) All drugs, (2) a set of innovator and generic drugs on a ''top 200 most prescribed'' list, and (3) the ''top 100'' or ''top 200'' drugs with the most adverse reactions. The agency believes including only labeling of new and more recently approved drug products is the best option for implementing the new format requirements (see comment 113). Even this limited set of products will require substantial resources from both industry and the agency for a period of several years. The agency's proposed implementation plan, which is being finalized in this rule as proposed, is intended to make the best use of these resources. Because there is a lack of standardized data on prescription volume and volumes can fluctuate considerably over time, the agency does not believe that categories based on volume would be prudent or feasible. As discussed in the preamble to the proposed rule (65 FR 81082 at 81098), the plan targets newer products because practitioners are more likely to refer to the labeling for newer products. Internal agency analysis finds that fully 40 percent of adverse reaction reports submitted to the FDA are for drugs approved within the last 3 years. Therefore, the agency rejected these three alternative categories in order to focus efforts on recently approved drug products whose labeling is more likely to be consulted by physicians.

4. Alternative Implementation Schedule

FDA considered a shorter implementation schedule of 3 years after the effective date for all applications and efficacy supplements approved 5 years prior to the effective date. The agency selected the more gradual implementation schedule of up to 7 years to reduce the cost impact of the rule, especially on small entities.

XII. Civil Justice Reform

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

XIII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procdure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR 601

Adminstrative practice and procedure, Biologics, Confidential business information.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 201, 314, and 601 are amended as follows:

PART 201—LABELING

■ 1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Section 201.56 is revised to read as follows:

§ 201.56 Requirements on content and format of labeling for human prescription drug and biological products.

(a) *General requirements*. Prescription drug labeling described in § 201.100(d) must meet the following general requirements:

(1) The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug.

(2) The labeling must be informative and accurate and neither promotional in tone nor false or misleading in any particular. In accordance with §§ 314.70 and 601.12 of this chapter, the labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading.

(3) The labeling must be based whenever possible on data derived from human experience. No implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness. Conclusions based on animal data but necessary for safe and effective use of the drug in humans must be identified as such and included with human data in the appropriate section of the labeling.

(b) *Categories of prescription drugs subject to the labeling content and format requirements in §§ 201.56(d) and 201.57*. (1) The following categories of prescription drug products are subject to the labeling requirements in paragraph (d) of this section and § 201.57 in accordance with the implementation schedule in paragraph (c) of this section:

(i) Prescription drug products for which a new drug application (NDA), biologics license application (BLA), or efficacy supplement was approved by the Food and Drug Administration (FDA) between June 30, 2001 and June 30, 2006;

(ii) Prescription drug products for which an NDA, BLA, or efficacy supplement is pending on June 30, 2006; or

(iii) Prescription drug products for which an NDA, BLA, or efficacy supplement is submitted anytime on or after June 30, 2006.

(2) Prescription drug products not described in paragraph (b)(1) of this section are subject to the labeling requirements in paragraph (e) of this section and § 201.80.

(c) *Schedule for implementing the labeling content and format requirements in §§ 201.56(d) and 201.57*. For products described in paragraph (b)(1) of this section, labeling conforming to the requirements in paragraph (d) of this section and § 201.57 must be submitted according to the following schedule:

(1) For products for which an NDA, BLA, or efficacy supplement is submitted for approval on or after June 30, 2006, proposed conforming labeling must be submitted as part of the application.

(2) For products for which an NDA, BLA, or efficacy supplement is pending on June 30, 2006, or that has been approved any time from June 30, 2005, up to and including June 30, 2006, a supplement with proposed conforming labeling must be submitted no later than June 30, 2009.

(3) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2004, up to and including June 29, 2005, a supplement with proposed conforming labeling must be submitted no later than June 30, 2010.

(4) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2003, up to and including June 29, 2004, a supplement with proposed conforming labeling must be submitted no later than June 30, 2011.

(5) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2002, up to and including June 29, 2003, a supplement with proposed conforming labeling must be submitted no later than June 30, 2012.

(6) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2001, up to and including June 29, 2002, a supplement with proposed conforming labeling must be submitted no later than June 30, 2013.

(d) *Labeling requirements for new and more recently approved prescription drug products*. This paragraph applies only to prescription drug products described in paragraph (b)(1) of this section and must be implemented according to the schedule specified in paragraph (c) of this section.

(1) Prescription drug labeling described in § 201.100(d) must contain the specific information required under § 201.57(a), (b), and (c) under the following headings and subheadings and in the following order:

Highlights of Prescribing Information
- Product Names, Other Required Information
- Boxed Warning
- Recent Major Changes
- Indications and Usage
- Dosage and Administration
- Dosage Forms and Strengths
- Contraindications
- Warnings and Precautions
- Adverse Reactions
- Drug Interactions
- Use in Specific Populations

Full Prescribing Information: Contents

Full Prescribing Information
- Boxed Warning
- 1 Indications and Usage
- 2 Dosage and Administration
- 3 Dosage Forms and Strengths
- 4 Contraindications
- 5 Warnings and Precautions
- 6 Adverse Reactions
- 7 Drug Interactions
- 8 Use in Specific Populations
  - 8.1 Pregnancy
  - 8.2 Labor and delivery
  - 8.3 Nursing mothers
  - 8.4 Pediatric use
  - 8.5 Geriatric use
- 9 Drug Abuse and Dependence
  - 9.1 Controlled substance
  - 9.2 Abuse
  - 9.3 Dependence
- 10 Overdosage
- 11 Description
- 12 Clinical Pharmacology
  - 12.1 Mechanism of action
  - 12.2 Pharmacodynamics
  - 12.3 Pharmacokinetics
- 13 Nonclinical Toxicology
  - 13.1 Carcinogenesis, mutagenesis, impairment of fertility
  - 13.2 Animal toxicology and/or pharmacology
- 14 Clinical Studies
- 15 References
- 16 How Supplied/Storage and Handling
- 17 Patient Counseling Information

(2) Additional nonstandard subheadings that are used to enhance labeling organization, presentation, or ease of use (e.g., for individual warnings or precautions, or for each drug interaction) must be assigned a decimal number that corresponds to their placement in labeling. The decimal numbers must be consistent with the standardized identifying numbers listed in paragraph (d)(1) of this section (e.g., subheadings added to the ''Warnings and Precautions'' section must be numbered 5.1, 5.2, and so on).

(3) Any reference in Highlights to information appearing in the full prescribing information must be accompanied by the identifying number (in parentheses) corresponding to the location of the information in the full prescribing information.

(4) Omit clearly inapplicable sections, subsections, or specific information. If sections or subsections required under paragraph (d)(1) of this section are omitted from the full prescribing information, the heading ''Full Prescribing Information: Contents'' must be followed by an asterisk and the following statement must appear at the end of Contents: ''* Sections or subsections omitted from the full prescribing information are not listed.''

(5) Any risk information that is required under § 201.57(c)(9)(iv) is considered ''appropriate pediatric contraindications, warnings, or precautions'' within the meaning of section 505A(l)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355A(l)(2)), whether such information appears in the ''Contraindications,'' ''Warnings and Precautions,'' or ''Use in Specific Populations'' section of labeling.

(e) *Labeling requirements for older prescription drug products*. This paragraph applies only to approved prescription drug products not described in paragraph (b)(1) of this section.

(1) Prescription drug labeling described in § 201.100(d) must contain the specific information required under § 201.80 under the following section headings and in the following order:
- Description
- Clinical Pharmacology
- Indications and Usage
- Contraindications
- Warnings
- Precautions
- Adverse Reactions
- Drug Abuse and Dependence
- Overdosage
- Dosage and Administration
- How Supplied

(2) The labeling may contain the following additional section headings if appropriate and if in compliance with § 201.80(l) and (m):
- Animal Pharmacology and/or Animal Toxicology
- Clinical Studies
- References

(3) Omit clearly inapplicable sections, subsections, or specific information.

(4) The labeling may contain a ''Product Title'' section preceding the ''Description'' section and containing only the information required by § 201.80(a)(1)(i), (a)(1)(ii), (a)(1)(iii), and (a)(1)(iv) and § 201.100(e). The information required by § 201.80(a)(1)(i) through (a)(1)(iv) must appear in the

''Description'' section of the labeling, whether or not it also appears in a ''Product Title.''

(5) The labeling must contain the date of the most recent revision of the labeling, identified as such, placed prominently immediately after the last section of the labeling.

(6) The requirement in § 201.80(f)(2) to reprint any FDA-approved patient labeling at the end of prescription drug labeling or accompany the prescription drug labeling must be implemented no later than June 30, 2007.

■ 3. Section 201.57 is redesignated as § 201.80 and new § 201.57 is added to read as follows:

§ 201.57 Specific requirements on content and format of labeling for human prescription drug and biological products described in § 201.56(b)(1).

The requirements in this section apply only to prescription drug products described in § 201.56(b)(1) and must be implemented according to the schedule specified in § 201.56(c), except for the requirement in paragraph (c)(18) of this section to reprint any FDA-approved patient labeling at the end of prescription drug labeling or accompany the prescription drug labeling, which must be implemented no later than June 30, 2007.

(a) *Highlights of prescribing information*. The following information must appear in all prescription drug labeling:

(1) *Highlights limitation statement*. The verbatim statement ''These highlights do not include all the information needed to use (*insert name of drug product*) safely and effectively. See full prescribing information for (insert name of drug product).''

(2) *Drug names, dosage form, route of administration, and controlled substance symbol*. The proprietary name and the established name of the drug, if any, as defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act (the act) or, for biological products, the proper name (as defined in § 600.3 of this chapter) including any appropriate descriptors. This information must be followed by the drug's dosage form and route of administration. For controlled substances, the controlled substance symbol designating the schedule in which the controlled substance is listed must be included as required by § 1302.04 of this chapter.

(3) *Initial U.S. approval*. The verbatim statement ''Initial U.S. Approval'' followed by the four-digit year in which FDA initially approved a new molecular entity, new biological product, or new combination of active ingredients. The statement must be placed on the line immediately beneath the established name or, for biological products, proper name of the product.

(4) *Boxed warning*. A concise summary of any boxed warning required by paragraph (c)(1) of this section, not to exceed a length of 20 lines. The summary must be preceded by a heading, in upper-case letters, containing the word ''WARNING'' and other words that are appropriate to identify the subject of the warning. The heading and the summary must be contained within a box and bolded. The following verbatim statement must be placed immediately following the heading of the boxed warning: ''See full prescribing information for complete boxed warning.''

(5) *Recent major changes*. A list of the section(s) of the full prescribing information, limited to the labeling sections described in paragraphs (c)(1), (c)(2), (c)(3), (c)(5), and (c)(6) of this section, that contain(s) substantive labeling changes that have been approved by FDA or authorized under § 314.70(c)(6) or (d)(2), or § 601.12(f)(1) through (f)(3) of this chapter. The heading(s) and, if appropriate, the subheading(s) of the labeling section(s) affected by the change must be listed together with each section's identifying number and the date (month/year) on which the change was incorporated in labeling. These labeling sections must be listed in the order in which they appear in the full prescribing information. A changed section must be listed under this heading in Highlights for at least 1 year after the date of the labeling change and must be removed at the first printing subsequent to the 1 year period.

(6) *Indications and usage*. A concise statement of each of the product's indications, as required under paragraph (c)(2) of this section, with any appropriate subheadings. Major limitations of use (e.g., lack of effect in particular subsets of the population, or second line therapy status) must be briefly noted. If the product is a member of an established pharmacologic class, the concise statement under this heading in Highlights must identify the class in the following manner: ''(Drug) is a (name of class) indicated for (indication(s)).''

(7) *Dosage and administration*. A concise summary of the information required under paragraph (c)(3) of this section, with any appropriate subheadings, including the recommended dosage regimen, starting dose, dose range, critical differences among population subsets, monitoring recommendations, and other clinically significant clinical pharmacologic information.

(8) *Dosage forms and strengths*. A concise summary of the information required under paragraph (c)(4) of this section, with any appropriate subheadings (e.g., tablets, capsules, injectable, suspension), including the strength or potency of the dosage form in metric system (e.g., 10-milligram tablets) and whether the product is scored.

(9) *Contraindications*. A concise statement of each of the product's contraindications, as required under paragraph (c)(5) of this section, with any appropriate subheadings.

(10) *Warnings and precautions*. A concise summary of the most clinically significant information required under paragraph (c)(6) of this section, with any appropriate subheadings, including information that would affect decisions about whether to prescribe a drug, recommendations for patient monitoring that are critical to safe use of the drug, and measures that can be taken to prevent or mitigate harm.

(11) *Adverse reactions*. (i) A list of the most frequently occurring adverse reactions, as described in paragraph (c)(7) of this section, along with the criteria used to determine inclusion (e.g., incidence rate). Adverse reactions important for other reasons (e.g., because they are serious or frequently lead to discontinuation or dosage adjustment) must not be repeated under this heading in Highlights if they are included elsewhere in Highlights (e.g., Warnings and Precautions, Contraindications).

(ii) For drug products other than vaccines, the verbatim statement ''To report SUSPECTED ADVERSE REACTIONS, contact (*insert name of manufacturer*) at (*insert manufacturer's phone number*) or FDA at (*insert current FDA phone number and Web address for voluntary reporting of adverse reactions*).''

(iii) For vaccines, the verbatim statement ''To report SUSPECTED ADVERSE REACTIONS, contact (*insert name of manufacturer*) at (*insert manufacturer's phone number*) or VAERS at (*insert the current VAERS phone number and Web address for voluntary reporting of adverse reactions*).''

(iv) For manufacturers with a Web site for voluntary reporting of adverse reactions, the Web address of the direct link to the site.

(12) *Drug interactions*. A concise summary of the information required under paragraph (c)(8) of this section, with any appropriate subheadings.

(13) *Use in specific populations*. A concise summary of the information required under paragraph (c)(9) of this section, with any appropriate subheadings.

(14) *Patient counseling information statement*. The verbatim statement ''See 17 for Patient Counseling Information'' or, if the product has FDA-approved patient labeling, the verbatim statement ''See 17 for Patient Counseling Information and (insert either FDA-approved patient labeling or Medication Guide).''

(15) *Revision date*. The date of the most recent revision of the labeling, identified as such, placed at the end of Highlights.

(b) *Full prescribing information: Contents*. Contents must contain a list of each heading and subheading required in the full prescribing information under § 201.56(d)(1), if not omitted under § 201.56(d)(4), preceded by the identifying number required under § 201.56(d)(1). Contents must also contain any additional subheading(s) included in the full prescribing information preceded by the identifying number assigned in accordance with § 201.56(d)(2).

(c) *Full prescribing information*. The full prescribing information must contain the information in the order required under paragraphs (c)(1) through (c)(18) of this section, together with the headings, subheadings, and identifying numbers required under § 201.56(d)(1), unless omitted under § 201.56(d)(4). If additional subheadings are used within a labeling section, they must be preceded by the identifying number assigned in accordance with § 201.56(d)(2).

(1) *Boxed warning*. Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box. The boxed warning ordinarily must be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. The box must contain, in uppercase letters, a heading inside the box that includes the word ''WARNING'' and conveys the general focus of the information in the box. The box must briefly explain the risk and refer to more detailed information in the ''Contraindications'' or ''Warnings and Precautions'' section, accompanied by the identifying number for the section or subsection containing the detailed information.

(2) *1 Indications and usage*. This section must state that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition.

(i) This section must include the following information when the conditions listed are applicable:

(A) If the drug is used for an indication only in conjunction with a primary mode of therapy (e.g., diet, surgery, behavior changes, or some other drug), a statement that the drug is indicated as an adjunct to that mode of therapy.

(B) If evidence is available to support the safety and effectiveness of the drug or biological product only in selected subgroups of the larger population (e.g., patients with mild disease or patients in a special age group), or if the indication is approved based on a surrogate endpoint under § 314.510 or § 601.41 of this chapter, a succinct description of the limitations of usefulness of the drug and any uncertainty about anticipated clinical benefits, with reference to the ''Clinical Studies'' section for a discussion of the available evidence.

(C) If specific tests are necessary for selection or monitoring of the patients who need the drug (e.g., microbe susceptibility tests), the identity of such tests.

(D) If information on limitations of use or uncertainty about anticipated clinical benefits is relevant to the recommended intervals between doses, to the appropriate duration of treatment when such treatment should be limited, or to any modification of dosage, a concise description of the information with reference to the more detailed information in the ''Dosage and Administration'' section.

(E) If safety considerations are such that the drug should be reserved for specific situations (e.g., cases refractory to other drugs), a statement of the information.

(F) If there are specific conditions that should be met before the drug is used on a long term basis (e.g., demonstration of responsiveness to the drug in a short term trial in a given patient), a statement of the conditions; or, if the indications for long term use are different from those for short term use, a statement of the specific indications for each use.

(ii) If there is a common belief that the drug may be effective for a certain use or if there is a common use of the drug for a condition, but the preponderance of evidence related to the use or condition shows that the drug is ineffective or that the therapeutic benefits of the product do not generally outweigh its risks, FDA may require that this section state that there is a lack of evidence that the drug is effective or safe for that use or condition.

(iii) Any statements comparing the safety or effectiveness of the drug with other agents for the same indication must, except for biological products, be supported by substantial evidence derived from adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(c) of this chapter. For biological products, such statements must be supported by substantial evidence.

(iv) For drug products other than biological products, all indications listed in this section must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(c) of this chapter. Indications or uses must not be implied or suggested in other sections of the labeling if not included in this section.

(v) For biological products, all indications listed in this section must be supported by substantial evidence of effectiveness. Indications or uses must not be implied or suggested in other sections of the labeling if not included in this section.

(3) *2 Dosage and administration*. (i) This section must state the recommended dose and, as appropriate:

(A) The dosage range,

(B) An upper limit beyond which safety and effectiveness have not been established, or beyond which increasing the dose does not result in increasing effectiveness,

(C) Dosages for each indication and subpopulation,

(D) The intervals recommended between doses,

(E) The optimal method of titrating dosage,

(F) The usual duration of treatment when treatment duration should be limited,

(G) Dosing recommendations based on clinical pharmacologic data (e.g., clinically significant food effects),

(H) Modification of dosage needed because of drug interactions or in special patient populations (e.g., in children, in geriatric age groups, in groups defined by genetic characteristics, or in patients with renal or hepatic disease),

(I) Important considerations concerning compliance with the dosage regimen,

(J) Efficacious or toxic concentration ranges and therapeutic concentration windows of the drug or its metabolites, if established and clinically significant.

Information on therapeutic drug concentration monitoring (TDM) must also be included in this section when TDM is necessary.

(ii) Dosing regimens must not be implied or suggested in other sections of the labeling if not included in this section.

(iii) Radiation dosimetry information must be stated for both the patient receiving a radioactive drug and the person administering it.

(iv) This section must also contain specific direction on dilution, preparation (including the strength of the final dosage solution, when prepared according to instructions, in terms of milligrams of active ingredient per milliliter of reconstituted solution, unless another measure of the strength is more appropriate), and administration of the dosage form, if needed (e.g., the rate of administration of parenteral drug in milligrams per minute; storage conditions for stability of the reconstituted drug, when important; essential information on drug incompatibilities if the drug is mixed in vitro with other drugs or diluents; and the following verbatim statement for parenterals: ''Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.'')

(4) *3 Dosage forms and strengths*. This section must contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible, including:

(i) The strength or potency of the dosage form in metric system (e.g., 10 milligram tablets), and, if the apothecary system is used, a statement of the strength in parentheses after the metric designation; and

(ii) A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting, when applicable. The National Drug Code number(s) for the drug product must not be included in this section.

(5) *4 Contraindications*. This section must describe any situations in which the drug should not be used because the risk of use (e.g., certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit. Those situations include use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by the drug and for whom no potential benefit makes the risk acceptable. Known hazards and not theoretical possibilities must be listed (e.g., if severe hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication). If no contraindications are known, this section must state ''None.''

(6) *5 Warnings and precautions*. (i) *General*. This section must describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (e.g., avoiding certain concomitant therapy), and steps that should be taken if they occur (e.g., dosage modification). The frequency of all clinically significant adverse reactions and the approximate mortality and morbidity rates for patients experiencing the reaction, if known and necessary for the safe and effective use of the drug, must be expressed as provided under paragraph (c)(7) of this section. In accordance with §§ 314.70 and 601.12 of this chapter, the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established. A specific warning relating to a use not provided for under the ''Indications and Usage'' section may be required by FDA in accordance with sections 201(n) and 502(a) of the act if the drug is commonly prescribed for a disease or condition and such usage is associated with a clinically significant risk or hazard.

(ii) *Other special care precautions*. This section must contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (e.g., precautions not required under any other specific section or subsection).

(iii) *Monitoring: Laboratory tests*. This section must identify any laboratory tests helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information must be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during, and after therapy.

(iv) *Interference with laboratory tests*. This section must briefly note information on any known interference by the product with laboratory tests and reference the section where the detailed information is presented (e.g., ''Drug Interactions'' section).

(7) *6 Adverse reactions*. This section must describe the overall adverse reaction profile of the drug based on the entire safety database. For purposes of prescription drug labeling, an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.

(i) *Listing of adverse reactions*. This section must list the adverse reactions that occur with the drug and with drugs in the same pharmacologically active and chemically related class, if applicable. The list or lists must be preceded by the information necessary to interpret the adverse reactions (e.g., for clinical trials, total number exposed, extent and nature of exposure).

(ii) *Categorization of adverse reactions*. Within a listing, adverse reactions must be categorized by body system, by severity of the reaction, or in order of decreasing frequency, or by a combination of these, as appropriate. Within a category, adverse reactions must be listed in decreasing order of frequency. If frequency information cannot be reliably determined, adverse reactions must be listed in decreasing order of severity.

(A) *Clinical trials experience*. This section must list the adverse reactions identified in clinical trials that occurred at or above a specified rate appropriate to the safety database. The rate of occurrence of an adverse reaction for the drug and comparators (e.g., placebo) must be presented, unless such data cannot be determined or presentation of comparator rates would be misleading. If adverse reactions that occurred below the specified rate are included, they must be included in a separate listing. If comparative rates of occurrence cannot be reliably determined (e.g., adverse reactions were observed only in the uncontrolled trial portion of the overall safety database), adverse reactions must be grouped within specified frequency ranges as appropriate to the safety database for the drug (e.g., adverse reactions occurring at a rate of less than 1/100, adverse reactions occurring at a rate of less than 1/500) or descriptively identified, if frequency ranges cannot be determined. For adverse reactions with significant clinical implications, the listings must be supplemented with additional detail about the nature, frequency, and

severity of the adverse reaction and the relationship of the adverse reaction to drug dose and demographic characteristics, if data are available and important.

(B) *Postmarketing experience*. This section of the labeling must list the adverse reactions, as defined in paragraph (c)(7) of this section, that are identified from domestic and foreign spontaneous reports. This listing must be separate from the listing of adverse reactions identified in clinical trials.

(iii) *Comparisons of adverse reactions between drugs*. For drug products other than biological products, any claim comparing the drug to which the labeling applies with other drugs in terms of frequency, severity, or character of adverse reactions must be based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(c) of this chapter. For biological products, any such claim must be based on substantial evidence.

(8) *7 Drug interactions*. (i) This section must contain a description of clinically significant interactions, either observed or predicted, with other prescription or over-the-counter drugs, classes of drugs, or foods (e.g., dietary supplements, grapefruit juice), and specific practical instructions for preventing or managing them. The mechanism(s) of the interaction, if known, must be briefly described. Interactions that are described in the ''Contraindications'' or ''Warnings and Precautions'' sections must be discussed in more detail under this section. Details of drug interaction pharmacokinetic studies that are included in the ''Clinical Pharmacology'' section that are pertinent to clinical use of the drug must not be repeated in this section.

(ii) This section must also contain practical guidance on known interference of the drug with laboratory tests.

(9) *8 Use in specific populations*. This section must contain the following subsections:

(i) *8.1 Pregnancy*. This subsection may be omitted only if the drug is not absorbed systemically and the drug is not known to have a potential for indirect harm to the fetus. For all other drugs, this subsection must contain the following information:

(A) *Teratogenic effects*. Under this subheading, the labeling must identify one of the following categories that applies to the drug, and the labeling must bear the statement required under the category:

(*1*) *Pregnancy category A*. If adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling must state: ''Pregnancy Category A. Studies in pregnant women have not shown that (*name of drug*) increases the risk of fetal abnormalities if administered during the first (*second, third, or all*) trimester(s) of pregnancy. If this drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, however, (*name of drug*) should be used during pregnancy only if clearly needed.'' The labeling must also contain a description of the human studies. If animal reproduction studies are also available and they fail to demonstrate a risk to the fetus, the labeling must also state: ''Reproduction studies have been performed in (kinds of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (name of drug).'' The labeling must also contain a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(*2*) *Pregnancy category B*. If animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women, the labeling must state: ''Pregnancy Category B. Reproduction studies have been performed in (*kind(s) of animal(s)*) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (*name of drug*). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.'' If animal reproduction studies have shown an adverse effect (other than decrease in fertility), but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling must state: ''Pregnancy Category B. Reproduction studies in (*kind(s) of animal(s)*) have shown (*describe findings*) at (x) times the human dose. Studies in pregnant women, however, have not shown that (name of drug) increases the risk of abnormalities when administered during the first (*second, third, or all*) trimester(s) of pregnancy. Despite the animal findings, it would appear that the possibility of fetal harm is remote, if the drug is used during pregnancy. Nevertheless, because the studies in humans cannot rule out the possibility of harm, (*name of drug*) should be used during pregnancy only if clearly needed.'' The labeling must also contain a description of the human studies and a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(*3*) Pregnancy category C. If animal reproduction studies have shown an adverse effect on the fetus, if there are no adequate and well-controlled studies in humans, and if the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks, the labeling must state: ''Pregnancy Category C. (*Name of drug*) has been shown to be teratogenic (or to have an embryocidal effect or other adverse effect) in (*name(s) of species*) when given in doses (x) times the human dose. There are no adequate and well-controlled studies in pregnant women. (*Name of drug*) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.'' The labeling must contain a description of the animal studies. If there are no animal reproduction studies and no adequate and well-controlled studies in humans, the labeling must state: ''Pregnancy Category C. Animal reproduction studies have not been conducted with (*name of drug*). It is also not known whether (*name of drug*) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. (*Name of drug*) should be given to a pregnant woman only if clearly needed.'' The labeling must contain a description of any available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(*4*) *Pregnancy category D*. If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling must state: ''Pregnancy Category D. See 'Warnings and Precautions' section.'' Under the ''Warnings and Precautions'' section, the labeling must state: ''(*Name of drug*) can cause fetal harm when administered to a pregnant woman. (*Describe the human data and any pertinent animal data.*) If this drug is used during pregnancy, or if the patient becomes

pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.''

(*5*) *Pregnancy category X*. If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling must state: ''Pregnancy Category X. See 'Contraindications' section.'' Under ''Contraindications,'' the labeling must state: ''(*Name of drug*) may (*can*) cause fetal harm when administered to a pregnant woman. (*Describe the human data and any pertinent animal data*.) (*Name of drug*) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.''

(B) *Nonteratogenic effects*. Under this subheading the labeling must contain other information on the drug's effects on reproduction and the drug's use during pregnancy that is not required specifically by one of the pregnancy categories, if the information is relevant to the safe and effective use of the drug. Information required under this heading must include nonteratogenic effects in the fetus or newborn infant (for example, withdrawal symptoms or hypoglycemia) that may occur because of a pregnant woman's chronic use of the drug for a preexisting condition or disease.

(ii) *8.2 Labor and delivery*. If the drug has a recognized use during labor or delivery (vaginal or abdominal delivery), whether or not the use is stated in the Indications and Usage section, this subsection must describe the available information about the effect of the drug on the mother and the fetus, on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of the newborn will be necessary, and the effect of the drug on the later growth, development, and functional maturation of the child. If any information required under this subsection is unknown, it must state that the information is unknown.

(iii) *8.3 Nursing mothers*. (A) If a drug is absorbed systemically, this subsection must contain, if known, information about excretion of the drug in human milk and effects on the nursing infant. Pertinent adverse effects observed in animal offspring must be described.

(B) If a drug is absorbed systemically and is known to be excreted in human milk, this subsection must contain one of the following statements, as appropriate. If the drug is associated with serious adverse reactions or if the drug has a known tumorigenic potential, the labeling must state: ''Because of the potential for serious adverse reactions in nursing infants from (*name of drug*) (or, ''Because of the potential for tumorigenicity shown for (*name of drug*) in (*animal or human*) studies), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.'' If the drug is not associated with serious adverse reactions and does not have a known tumorigenic potential, the labeling must state: ''Caution should be exercised when (*name of drug*) is administered to a nursing woman.''

(C) If a drug is absorbed systemically and information on excretion in human milk is unknown, this subsection must contain one of the following statements, as appropriate. If the drug is associated with serious adverse reactions or has a known tumorigenic potential, the labeling must state: ''It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from (*name of drug*) (or, ''Because of the potential for tumorigenicity shown for (*name of drug*) in (*animal or human*) studies), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.'' If the drug is not associated with serious adverse reactions and does not have a known tumorigenic potential, the labeling must state: ''It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when (*name of drug*) is administered to a nursing woman.''

(iv) *8.4 Pediatric use*. (A) Pediatric population(s)/pediatric patient(s): For the purposes of paragraphs (c)(9)(iv)(B) through (c)(9)(iv)(H) of this section, the terms *pediatric population(s)* and *pediatric patient(s)* are defined as the pediatric age group, from birth to 16 years, including age groups often called neonates, infants, children, and adolescents.

(B) If there is a specific pediatric indication different from those approved for adults that is supported by adequate and well-controlled studies in the pediatric population, it must be described under the ''Indications and Usage'' section, and appropriate pediatric dosage information must be given under the ''Dosage and Administration'' section. The ''Pediatric use'' subsection must cite any limitations on the pediatric indication, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. Data summarized in this subsection should be discussed in more detail, if appropriate, under the ''Clinical Pharmacology'' or ''Clinical Studies'' section. As appropriate, this information must also be contained in the ''Contraindications'' and/or ''Warnings and Precautions'' section(s).

(C) If there are specific statements on pediatric use of the drug for an indication also approved for adults that are based on adequate and well-controlled studies in the pediatric population, they must be summarized in the ''Pediatric use'' subsection and discussed in more detail, if appropriate, under the ''Clinical Pharmacology'' and ''Clinical Studies'' sections. Appropriate pediatric dosage must be given under the ''Dosage and Administration'' section. The ''Pediatric use'' subsection of the labeling must also cite any limitations on the pediatric use statement, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. As appropriate, this information must also be contained in the ''Contraindications'' and/or ''Warnings and Precautions'' section(s).

(D)(*1*) When a drug is approved for pediatric use based on adequate and well-controlled studies in adults with other information supporting pediatric use, the ''Pediatric use'' subsection of the labeling must contain either the following statement or a reasonable alternative:

The safety and effectiveness of (*drug name*) have been established in the age groups ___ to ___ (note any limitations, e.g., no data for pediatric patients under 2, or only applicable to certain indications approved in adults). Use of (*drug name*) in these age groups is supported by evidence from adequate and well-controlled studies of (*drug name*) in adults with additional data (*insert wording that accurately describes the data submitted to support a finding of substantial evidence of effectiveness in the pediatric population*).

(*2*) Data summarized in the preceding prescribed statement in this subsection must be discussed in more detail, if appropriate, under the ''Clinical

Pharmacology'' or the ''Clinical Studies'' section. For example, pediatric pharmacokinetic or pharmacodynamic studies and dose response information should be described in the ''Clinical Pharmacology'' section. Pediatric dosing instructions must be included in the ''Dosage and Administration'' section. Any differences between pediatric and adult responses, need for specific monitoring, dosing adjustments, and any other information related to safe and effective use of the drug in pediatric patients must be cited briefly in the ''Pediatric use'' subsection and, as appropriate, in the ''Contraindications,'' ''Warnings and Precautions,'' and ''Dosage and Administration'' sections.

(E) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for a particular pediatric population, the ''Pediatric use'' subsection must contain an appropriate statement such as ''Safety and effectiveness in pediatric patients below the age of (__) have not been established.'' If use of the drug in this pediatric population is associated with a specific hazard, the hazard must be described in this subsection, or, if appropriate, the hazard must be stated in the ''Contraindications'' or ''Warnings and Precautions'' section and this subsection must refer to it.

(F) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for any pediatric population, this subsection must contain the following statement: ''Safety and effectiveness in pediatric patients have not been established.'' If use of the drug in premature or neonatal infants, or other pediatric subgroups, is associated with a specific hazard, the hazard must be described in this subsection, or, if appropriate, the hazard must be stated in the ''Contraindications'' or ''Warnings and Precautions'' section and this subsection must refer to it.

(G) If the sponsor believes that none of the statements described in paragraphs (c)(9)(iv)(B) through (c)(9)(iv)(F) of this section are appropriate or relevant to the labeling of a particular drug, the sponsor must provide reasons for omission of the statements and may propose alternative statement(s). FDA may permit use of an alternative statement if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling and that the alternative statement is accurate and appropriate.

(H) If the drug product contains one or more inactive ingredients that present an increased risk of toxic effects to neonates or other pediatric subgroups, a special note of this risk must be made, generally in the ''Contraindications'' or ''Warnings and Precautions'' section.

(v) *8.5 Geriatric use.* (A) A specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population must be described under the ''Indications and Usage'' section, and appropriate geriatric dosage must be stated under the ''Dosage and Administration'' section. The ''Geriatric use'' subsection must cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. Unless otherwise noted, information contained in the ''Geriatric use'' subsection must pertain to use of the drug in persons 65 years of age and older. Data summarized in this subsection must be discussed in more detail, if appropriate, under ''Clinical Pharmacology'' or the ''Clinical Studies'' section. As appropriate, this information must also be contained in the ''Warnings and Precautions'' and/or ''Contraindications'' section(s).

(B) Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric indication, must be contained in the ''Geriatric use'' subsection and must reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. This information includes detailed results from controlled studies that are available to the sponsor and pertinent information from well-documented studies obtained from a literature search. Controlled studies include those that are part of the marketing application and other relevant studies available to the sponsor that have not been previously submitted in the investigational new drug application, new drug application, biologics license application, or a supplement or amendment to one of these applications (e.g., postmarketing studies or adverse drug reaction reports). The ''Geriatric use'' subsection must contain the following statement(s) or reasonable alternative, as applicable, taking into account available information:

(*1*) If clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects, and other reported clinical experience has not identified such differences, the ''Geriatric use'' subsection must include the following statement:

Clinical studies of (*name of drug*) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

(*2*) If clinical studies (including studies that are part of marketing applications and other relevant studies available to the sponsor that have not been submitted in the sponsor's applications) included enough elderly subjects to make it likely that differences in safety or effectiveness between elderly and younger subjects would have been detected, but no such differences (in safety or effectiveness) were observed, and other reported clinical experience has not identified such differences, the ''Geriatric use'' subsection must contain the following statement:

Of the total number of subjects in clinical studies of (*name of drug*), __ percent were 65 and over, while __ percent were 75 and over. (Alternatively, the labeling may state the total number of subjects included in the studies who were 65 and over and 75 and over.) No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

(*3*) If evidence from clinical studies and other reported clinical experience available to the sponsor indicates that use of the drug in elderly patients is associated with differences in safety or effectiveness, or requires specific monitoring or dosage adjustment, the ''Geriatric use'' subsection must contain a brief description of observed differences or specific monitoring or dosage requirements and, as appropriate, must refer to more detailed discussions in the ''Contraindications,'' ''Warnings and Precautions,'' ''Dosage and Administration,'' or other sections.

(C)(*1*) If specific pharmacokinetic or pharmacodynamic studies have been carried out in the elderly, they must be described briefly in the ''Geriatric use'' subsection and in detail under the ''Clinical Pharmacology'' section. The ''Clinical Pharmacology'' and ''Drug Interactions'' sections ordinarily contain

information on drug/disease and drug/drug interactions that is particularly relevant to the elderly, who are more likely to have concomitant illness and to use concomitant drugs.

(*2*) If a drug is known to be substantially excreted by the kidney, the ''Geriatric use'' subsection must include the statement:

This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

(D) If use of the drug in the elderly appears to cause a specific hazard, the hazard must be described in the ''Geriatric use'' subsection, or, if appropriate, the hazard must be stated in the ''Contraindications'' or ''Warnings and Precautions'' section, and the ''Geriatric use'' subsection must refer to those sections.

(E) Labeling under paragraphs (c)(9)(v)(A) through (c)(9)(v)(C) of this section may include statements, if they are necessary for safe and effective use of the drug, and reflect good clinical practice or past experience in a particular situation, e.g., for a sedating drug, it could be stated that:

Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses of (*name of drug*) and observed closely.

(F) If the sponsor believes that none of the requirements described in paragraphs (c)(9)(v)(A) through (c)(9)(v)(E) of this section are appropriate or relevant to the labeling of a particular drug, the sponsor must provide reasons for omission of the statements and may propose an alternative statement. FDA may permit omission of the statements if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling. FDA may permit use of an alternative statement if the agency determines that such statement is accurate and appropriate.

(vi) *Additional subsections*. Additional subsections may be included, as appropriate, if sufficient data are available concerning the use of the drug in other specified subpopulations (e.g., renal or hepatic impairment).

(10) *9 Drug abuse and dependence*. This section must contain the following information, as appropriate:

(i) *9.1 Controlled substance*. If the drug is controlled by the Drug Enforcement Administration, the schedule in which it is controlled must be stated.

(ii) *9.2 Abuse*. This subsection must state the types of abuse that can occur with the drug and the adverse reactions pertinent to them, and must identify particularly susceptible patient populations. This subsection must be based primarily on human data and human experience, but pertinent animal data may also be used.

(iii) *9.3 Dependence*. This subsection must describe characteristic effects resulting from both psychological and physical dependence that occur with the drug and must identify the quantity of the drug over a period of time that may lead to tolerance or dependence, or both. Details must be provided on the adverse effects of chronic abuse and the effects of abrupt withdrawal. Procedures necessary to diagnose the dependent state and the principles of treating the effects of abrupt withdrawal must be described.

(11) *10 Overdosage*. This section must be based on human data. If human data are unavailable, appropriate animal and in vitro data may be used. The following specific information must be provided:

(i) Signs, symptoms, and laboratory findings associated with an overdosage of the drug;

(ii) Complications that can occur with the drug (for example, organ toxicity or delayed acidosis);

(iii) Concentrations of the drug in biologic fluids associated with toxicity or death; physiologic variables influencing excretion of the drug, such as urine pH; and factors that influence the dose response relationship of the drug, such as tolerance. The pharmacokinetic data given in the ''Clinical Pharmacology'' section also may be referenced here, if applicable to overdoses;

(iv) The amount of the drug in a single dose that is ordinarily associated with symptoms of overdosage and the amount of the drug in a single dose that is likely to be life threatening;

(v) Whether the drug is dialyzable; and

(vi) Recommended general treatment procedures and specific measures for support of vital functions (e.g., proven antidotes, gastric lavage, forced diuresis, or as per Poison Control Center). Such recommendations must be based on data available for the specific drug or experience with pharmacologically related drugs. Unqualified recommendations for which data are lacking for the specific drug or class of drugs must not be stated.

(12) *11 Description*. (i) This section must contain:

(A) The proprietary name and the established name, if any, as defined in section 502(e)(2) of the act, of the drug or, for biological products, the proper name (as defined in § 600.3 of this chapter) and any appropriate descriptors;

(B) The type of dosage form(s) and the route(s) of administration to which the labeling applies;

(C) The same qualitative and/or quantitative ingredient information as required under § 201.100(b) for drug labels or §§ 610.60 and 610.61 of this chapter for biological product labels;

(D) If the product is sterile, a statement of that fact;

(E) The pharmacological or therapeutic class of the drug;

(F) For drug products other than biological products, the chemical name and structural formula of the drug; and

(G) If the product is radioactive, a statement of the important nuclear physical characteristics, such as the principal radiation emission data, external radiation, and physical decay characteristics.

(ii) If appropriate, other important chemical or physical information, such as physical constants or pH, must be stated.

(13) *12 Clinical pharmacology*. (i) This section must contain information relating to the human clinical pharmacology and actions of the drug in humans. Pharmacologic information based on in vitro data using human biomaterials or pharmacologic animal models, or relevant details about in vivo study designs or results (e.g., drug interaction studies), may be included in this section if essential to understand dosing or drug interaction information presented in other sections of the labeling. This section must include the following subsections:

(A) *12.1 Mechanism of action*. This subsection must summarize what is known about the established mechanism(s) of the drug's action in humans at various levels (e.g., receptor, membrane, tissue, organ, whole body). If the mechanism of action is not known, this subsection must contain a statement about the lack of information.

(B) *12.2 Pharmacodynamics*. This subsection must include a description of any biochemical or physiologic pharmacologic effects of the drug or active metabolites related to the drug's clinical effect in preventing, diagnosing, mitigating, curing, or treating disease, or those related to adverse effects or toxicity. Exposure-response relationships (e.g., concentration-response, dose-response) and time course of pharmacodynamic response (including short-term clinical response) must be included if known. If this information is unknown, this subsection must contain a statement about the lack

of information. Detailed dosing or monitoring recommendations based on pharmacodynamic information that appear in other sections (e.g., ''Warnings and Precautions'' or ''Dosage and Administration'') must not be repeated in this subsection, but the location of such recommendations must be referenced.

(C) *12.3 Pharmacokinetics*. This subsection must describe the clinically significant pharmacokinetics of a drug or active metabolites, (i.e., pertinent absorption, distribution, metabolism, and excretion parameters). Information regarding bioavailability, the effect of food, minimum concentration (C_{min}), maximum concentration (C_{max}), time to maximum concentration (T_{max}), area under the curve (AUC), pertinent half-lives ($t_{1/2}$), time to reach steady state, extent of accumulation, route(s) of elimination, clearance (renal, hepatic, total), mechanisms of clearance (e.g., specific enzyme systems), drug/drug and drug/food (e.g., dietary supplements, grapefruit juice) pharmacokinetic interactions (including inhibition, induction, and genetic characteristics), and volume of distribution (V_d) must be presented if clinically significant. Information regarding nonlinearity in pharmacokinetic parameters, changes in pharmacokinetics over time, and binding (plasma protein, erythrocyte) parameters must also be presented if clinically significant. This section must also include the results of pharmacokinetic studies (e.g., of metabolism or interaction) that establish the absence of an effect, including pertinent human studies and in vitro data. Dosing recommendations based on clinically significant factors that change the product's pharmacokinetics (e.g., age, gender, race, hepatic or renal dysfunction, concomitant therapy) that appear in other sections (e.g., ''Warnings and Precautions,'' ''Dosage and Administration'' or ''Use in Specific Populations'') must not be repeated in this subsection, but the location of such recommendations must be referenced.

(ii) Data that demonstrate activity or effectiveness in in vitro or animal tests and that have not been shown by adequate and well-controlled clinical studies to be pertinent to clinical use may be included under this section only under the following circumstances:

(A) In vitro data for anti-infective drugs may be included if the data are immediately preceded by the statement ''The following in vitro data are available but their clinical significance is unknown.''

(B) For other classes of drugs, in vitro and animal data that have not been shown by adequate and well-controlled studies, as defined in § 314.126(b) of this chapter, to be necessary for the safe and effective use may be included in this section only if a waiver is granted under § 201.58 or § 314.126(c) of this chapter.

(14) *13 Nonclinical toxicology*. This section must contain the following subsections as appropriate:

(i) *13.1 Carcinogenesis, mutagenesis, impairment of fertility*. This subsection must state whether long term studies in animals have been performed to evaluate carcinogenic potential and, if so, the species and results. If results from reproduction studies or other data in animals raise concern about mutagenesis or impairment of fertility in either males or females, this must be described. Any precautionary statement on these topics must include practical, relevant advice to the prescriber on the significance of these animal findings. Human data suggesting that the drug may be carcinogenic or mutagenic, or suggesting that it impairs fertility, as described in the ''Warnings and Precautions'' section, must not be included in this subsection of the labeling.

(ii) *13.2 Animal toxicology and/or pharmacology*. Significant animal data necessary for safe and effective use of the drug in humans that is not incorporated in other sections of labeling must be included in this section (e.g., specifics about studies used to support approval under § 314.600 or § 601.90 of this chapter, the absence of chronic animal toxicity data for a drug that is administered over prolonged periods or is implanted in the body).

(15) *14 Clinical studies*. This section must discuss those clinical studies that facilitate an understanding of how to use the drug safely and effectively. Ordinarily, this section will describe the studies that support effectiveness for the labeled indication(s), including discussion of study design, population, endpoints, and results, but must not include an encyclopedic listing of all, or even most, studies performed as part of the product's clinical development program. If a specific important clinical study is mentioned in any section of the labeling required under §§ 201.56 and 201.57 because the study is essential to an understandable presentation of the information in that section of the labeling, any detailed discussion of the study must appear in this section.

(i) For drug products other than biological products, any clinical study that is discussed in prescription drug labeling that relates to an indication for or use of the drug must be adequate and well-controlled as described in § 314.126(b) of this chapter and must not imply or suggest indications or uses or dosing regimens not stated in the ''Indications and Usage'' or ''Dosage and Administration'' section. For biological products, any clinical study that is discussed that relates to an indication for or use of the biological product must constitute or contribute to substantial evidence and must not imply or suggest indications or uses or dosing regimens not stated in the ''Indications and Usage'' or ''Dosage and Administration'' section.

(ii) Any discussion of a clinical study that relates to a risk from the use of the drug must also refer to the other sections of the labeling where the risk is identified or discussed.

(16) *15 References*. When prescription drug labeling must summarize or otherwise rely on a recommendation by an authoritative scientific body, or on a standardized methodology, scale, or technique, because the information is important to prescribing decisions, the labeling may include a reference to the source of the information.

(17) *16 How supplied/storage and handling*. This section must contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible. The information must include, as appropriate:

(i) The strength or potency of the dosage form in metric system (e.g., 10 milligram tablets) and, if the apothecary system is used, a statement of the strength in parentheses after the metric designation;

(ii) The units in which the dosage form is ordinarily available for prescribing by practitioners (e.g., bottles of 100);

(iii) Appropriate information to facilitate identification of the dosage forms, such as shape, color, coating, scoring, imprinting, and National Drug Code number; and

(iv) Special handling and storage conditions.

(18) *17 Patient counseling information*. This section must contain information necessary for patients to use the drug safely and effectively (e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects). Any FDA-approved patient labeling must be referenced in this section and the full text of such patient labeling must be reprinted immediately following this section or, alternatively, accompany the prescription drug labeling. Any FDA-approved patient labeling printed immediately following this section or

accompanying the labeling is subject to the type size requirements in paragraph (d)(6) of this section, except for a Medication Guide to be detached and distributed to patients in compliance with § 208.24 of this chapter. Medication Guides for distribution to patients are subject to the type size requirements set forth in § 208.20 of this chapter.

(d) *Format requirements*. All labeling information required under paragraphs (a), (b), and (c) of this section must be printed in accordance with the following specifications:

(1) All headings and subheadings required by paragraphs (a) and (c) of this section must be highlighted by bold type that prominently distinguishes the headings and subheadings from other labeling information. Reverse type is not permitted as a form of highlighting.

(2) A horizontal line must separate the information required by paragraphs (a), (b), and (c) of this section.

(3) The headings listed in paragraphs (a)(5) through (a)(13) of this section must be presented in the center of a horizontal line.

(4) If there are multiple subheadings listed under paragraphs (a)(4) through (a)(13) of this section, each subheading must be preceded by a bullet point.

(5) The labeling information required by paragraphs (a)(1) through (a)(4), (a)(11)(ii) through (a)(11)(iv), and (a)(14) of this section must be in bold print.

(6) The letter height or type size for all labeling information, headings, and subheadings set forth in paragraphs (a), (b), and (c) of this section must be a minimum of 8 points, except for labeling information that is on or within the package from which the drug is to be dispensed, which must be a minimum of 6 points.

(7) The identifying numbers required by § 201.56(d) and paragraphs (c)(1) through (c)(18) of this section must be presented in bold print and must precede the heading or subheading by at least two square em's (i.e., two squares of the size of the letter ''m'' in 8 point type).

(8) The information required by paragraph (a) of this section, not including the information required under paragraph (a)(4) of this section, must be limited in length to an amount that, if printed in 2 columns on a standard sized piece of typing paper (8 1/2 by 11 inches), single spaced, in 8 point type with 1/2-inch margins on all sides and between columns, would fit on one-half of the page.

(9) Sections or subsections of labeling that are identified as containing recent major changes under paragraph (a)(5) of this section must be highlighted in the full prescribing information by the inclusion of a vertical line on the left edge of the new or modified text.

(10) For the information required by paragraph (b) of this section, each section heading must be in bold print. Each subheading within a section must be indented and not bolded.

■ 4. Section 201.58 is revised to read as follows:

§ 201.58 Waiver of labeling requirements.

An applicant may ask the Food and Drug Administration to waive any requirement under §§ 201.56, 201.57, and 201.80. A waiver request must be submitted in writing to the Director (or the Director's designee), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or, if applicable, the Director (or the Director's designee), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200 North, Rockville, MD 20852–1448. The waiver must be granted or denied in writing by the Director or the Director's designee.

§ 201.59 [Removed]

■ 5. Section 201.59 is removed.

■ 6. Newly redesignated § 201.80 is amended by:

a. Revising the section heading;

b. Amending paragraphs (b)(2)(ii), (c)(3)(i), (c)(3)(v), and (g)(4) by removing the phrase ''§ 314.126(b)'' the second time it appears and by adding in its place the phrase ''§ 314.126(c)'';

c. Removing the phrase ''induced emesis,'' in paragraph (i)(6);

d. Revising paragraphs (c)(2), (f)(2), and (m)(1); and

e. Adding a new sentence after the first sentence of paragraph (j).

The additions and revisions read as follows:

§ 201.80 Specific requirements on content and format of labeling for human prescription drug and biological products; older drugs not described in § 201.56(b)(1).

* * * * *

(c) * * *

(2)(i) For drug products other than biological products, all indications listed in this section must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(c) of this chapter. Indications or uses must not be implied or suggested in other sections of labeling if not included in this section.

(ii) For biological products, all indications listed in this section must be supported by substantial evidence of effectiveness. Indications or uses must not be implied or suggested in other sections of labeling if not included in this section.

* * * * *

(f) * * *

(2) *Information for patients*. This subsection must contain information necessary for patients to use the drug safely and effectively (e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects). Any FDA-approved patient labeling must be referenced in this section and the full text of such patient labeling must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling. The type size requirement for the Medication Guide set forth in § 208.20 of this chapter does not apply to the Medication Guide that is reprinted in or accompanying the prescription drug labeling unless such Medication Guide is to be detached and distributed to patients in compliance with § 208.24 of this chapter.

* * * * *

(j) *Dosage and administration*. * * * Dosing regimens must not be implied or suggested in other sections of labeling if not included in this section. * * *

* * * * *

(m) * * *

(1)(i) If the clinical study is cited in the labeling in place of a detailed discussion of data and information concerning an indication for use of the drug, the clinical study must constitute an adequate and well-controlled study as described in § 314.126(b) of this chapter, except for biological products, and must not imply or suggest indications or uses or dosing regimens not stated in the ''Indications and Usage'' or ''Dosage and Administration'' section.

(ii) When prescription drug labeling must summarize or otherwise rely on a recommendation by an authoritative scientific body, or on a standardized methodology, scale, or technique, because the information is important to prescribing decisions, the labeling may include a reference to the source of the information.

* * * * *

■ 7. Section 201.100 is amended by revising paragraph (d)(3) to read as follows:

§ 201.100 Prescription drugs for human use.

* * * * *

(d) * * *

(3) The information required, and in the format specified, by §§ 201.56, 201.57, and 201.80.

* * * * *

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 8. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

■ 9. Section 314.70 is amended by:

a. Removing from paragraph (b)(2)(v)(B) the phrase ''(b)(8)(iv) of this chapter.'' and adding in its place the phrase ''(b)(8)(iv) of this chapter; and'';

b. Adding paragraph (b)(2)(v)(C);

c. Revising the introductory text of paragraph (c)(6)(iii); and

d. Revising paragraph (d)(2)(x).

The additions and revisions read as follows:

§ 314.70 Supplements and other changes to an approved application.

* * * * *

(b) * * *

(2) * * *

(v) * * *

(C) Any change to the information required by § 201.57(a) of this chapter, with the following exceptions that may be reported in an annual report under paragraph (d)(2)(x) of this section:

(*1*) Removal of a listed section(s) specified in § 201.57(a)(5) of this chapter; and

(*2*) Changes to the most recent revision date of the labeling as specified in § 201.57(a)(15) of this chapter.

* * * * *

(c) * * *

(6) * * *

(iii) Changes in the labeling, except for changes to the information required in § 201.57(a) of this chapter (which must be made pursuant to paragraph (b)(2)(v)(C) of this section), to accomplish any of the following:

* * * * *

(d) * * *

(2) * * *

(x) An editorial or similar minor change in labeling, including a change to the information allowed by paragraphs (b)(2)(v)(C)(*1*) and (*2*) of this section.

* * * * *

PART 601—LICENSING

■ 10. The authority cite for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

■ 11. Section 601.12 is amended by:

a. Adding two sentences after the second sentence and before the third sentence in paragraph (f)(1);

b. Revising the introductory text of paragraph (f)(2)(i);

c. Removing from paragraph (f)(3)(i)(B) the word ''and'';

d. Removing from paragraph (f)(3)(i)(C) the phrase ''Medication Guide.'' and adding in its place the phrase ''Medication Guide; and''; and

e. Adding paragraph (f)(3)(i)(D).

The additions and revisions read as follows:

§ 601.12 Changes to an approved application.

* * * * *

(f) * * *

(1) * * * An applicant cannot use paragraph (f)(2) of this section to make any change to the information required in § 201.57(a) of this chapter. An applicant may report the minor changes to the information specified in paragraph (f)(3)(i)(D) of this section in an annual report. * * *

(2) * * *

(i) An applicant shall submit, at the time such change is made, a supplement for any change in the package insert, package label, or container label, except for changes to the package insert required in § 201.57(a) of this chapter (which must be made pursuant to paragraph (f)(1) of this section), to accomplish any of the following:

* * * * *

(f) * * *

(3) * * *

(i) * * *

(D) A change to the information required in § 201.57(a) of this chapter as follows:

(*1*) Removal of a listed section(s) specified in § 201.57(a)(5) of this chapter; and

(*2*) Changes to the most recent revision date of the labeling as specified in § 201.57(a)(15) of this chapter.

* * * * *

Dated: December 7, 2005.

Andrew C. von Eschenbach,

Acting Commissioner of Food and Drugs.

Dated: December 7, 2005.

Michael O. Leavitt,

Secretary of Health and Human Services.

[FR Doc. 06–545 Filed 1–18–06; 10:28 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0011]

Draft Guidances for Industry on the Content and Format of Labeling for Human Prescription Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft guidances for industry entitled ''Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements'' and ''Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' These draft guidances are two of a series of guidance documents intended to assist applicants in complying with the new requirements in the final rule on the content and format of labeling for prescription drug and biological products published elsewhere in this issue of the **Federal Register**. Elsewhere in this issue of the **Federal Register**, the agency is announcing the availability of two guidances on the content and format of the ''Clinical Studies'' and ''Adverse Reactions'' sections of labeling.

DATES: Submit written or electronic comments on the draft guidances by April 24, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFD–040), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The draft guidances may also be obtained by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

FOR FURTHER INFORMATION CONTACT:

Janet Norden, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 10903 New Hampshire Ave., bldg. W022, rm. 4202, Silver Spring, MD 20993, 301–796–2270, or

Toni Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 22, 2000 (65 FR 81082), FDA published a proposed rule to revise the content and format of prescription drug labeling. The agency's final rule amending the requirements for the content and format of labeling for human prescription drug and biological products is published elsewhere in this issue of the **Federal Register**. The new regulations are designed to make information in prescription drug labeling easier for health care practitioners to access, read, and use; thereby increasing the extent to which practitioners rely on labeling for prescribing decisions. The final rule requires that labeling of new and recently approved products include highlights of prescribing information and a table of contents. It reorders certain sections of labeling, based on the importance of the information to practitioners and the frequency with which practitioners refer to a section, and makes minor content changes.

II. The Draft Guidances

FDA is developing guidance on how to implement the new requirements as well as a series of guidances on selected sections of prescription drug labeling. This document announces the availability of two draft guidances entitled ''Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements'' and ''Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' FDA developed these draft guidances to accompany the publication of the final rule, published elsewhere in this issue of the **Federal Register**, on the content and format of prescription drug labeling.

- The draft guidance entitled ''Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements'' provides recommendations on issues to consider when revising labeling for approved products to meet the new requirements, issues to consider when developing highlights of prescribing information, how to format labeling, and other procedural information.
- The draft guidance entitled ''Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format'' provides recommendations on how to select, characterize, and organize information for inclusion in the ''Warnings and Precautions'' and ''Contraindications'' sections, as well as what information to include in a boxed warning.

Elsewhere in this issue of the **Federal Register**, the agency is announcing the availability of guidances on the content and format of the ''Clinical Studies'' and ''Adverse Reactions'' sections of labeling. These final guidances were previously published in draft for comment.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent the agency's current thinking on these topics. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidances. Submit a single copy of electronic commments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should identify clearly which guidance they are commenting on and should be identified with the docket number found in brackets in the heading of this document. The draft guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

These draft guidances contain information collection provisions that

are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information in the draft guidances are estimated in section ''VIII. Paperwork Reduction Act of 1995'' of the final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,'' published elsewhere in this issue of the **Federal Register**.

V. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–543 Filed 1–18–06; 10:28 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2000D–1306 (formerly 00D–1306) and 2001D–0269 (formerly 01D–0269)]

Two Guidances for Industry on the Content and Format of Labeling for Human Prescription Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two guidances for industry entitled ''Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' and ''Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' These guidances are two of a series of guidance documents intended to assist applicants in complying with the new requirements in the final rule on the content and format of labeling for human prescription drug and biological products published elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of these guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidances may also be obtained by calling CBER at 1–800–835–4709 or 301 827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to guidance documents.

FOR FURTHER INFORMATION CONTACT:

Janet Norden, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., bldg. WO22, rm. 4202, Silver Spring, MD 20993, 301–796–2270, or

Toni Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 22, 2000 (65 FR 81082), FDA published a proposed rule to revise the content and format of prescription drug labeling. The agency's final rule amending the requirements for the content and format of labeling for human prescription drug and biological products is published elsewhere in this issue of the **Federal Register**. The new regulations are designed to make information in prescription drug labeling easier for health care practitioners to access, read, and use, thereby increasing the extent to which practitioners rely on labeling for prescribing decisions. Among other changes, the final rule makes minor content changes and reorders certain sections of labeling, based on the importance of the information to practitioners and the frequency with which practitioners refer to a section.

II. The Guidances

FDA is developing a series of guidances on selected sections of prescription drug labeling, as well as guidance on how to implement the new requirements. This notice announces the availability of two guidance documents, entitled ''Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' and ''Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' As described later in this document, these two guidances were previously published for comment.

The guidances are intended to help applicants and reviewers do the following: (1) Select information for inclusion in the ''Adverse Reactions'' and ''Clinical Studies'' sections of prescription drug labeling; (2) characterize information selected for inclusion in these sections; and (3) organize and present the information, including use of graphs and tables, within these sections.

- The guidance entitled ''Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' provides recommendations on the ''Adverse Reactions'' section of labeling. In the **Federal Register** of June 21, 2000 (65 FR 38563), FDA published a document announcing the availability of a draft guidance for industry entitled ''Content and Format of the Adverse Reactions Section of Labeling for Human Drugs and Biologics.'' The agency received 14 comments from nine pharmaceutical firms, a trade organization, a pharmacy professional society, a health insurance company, a medical publishing company, and a consumer. In response to these comments, the agency made a number of revisions to the draft guidance. Most significantly, the final guidance makes recommendations on how to make the most clinically important information accessible to health care practitioners. It provides recommendations on how to characterize and organize information and it clarifies the recommended criteria for determining when to include low frequency adverse events in the ''Adverse Reactions'' section.
- The guidance entitled ''Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' provides recommendations on the ''Clinical Studies'' section of labeling. In the **Federal Register** of July 9, 2001 (66 FR 35797), FDA published a document announcing the availability of a draft guidance for industry entitled ''Content and Format of the Clinical Studies Section of Labeling for Human Drugs and Biologics.'' The agency received seven comments from six pharmaceutical firms and one trade

organization. In response to these comments, the agency has made revisions to the draft guidance. The final guidance provides several examples of the types of studies that can be included in the ''Clinical Studies'' section. The final guidance also provides clarification on when it is appropriate to include comparative data.

Elsewhere in this issue of the **Federal Register**, the agency is making available for comment draft guidances on implementing the content and format requirements and on the ''Warnings and Precautions,'' ''Contraindications,'' and ''Boxed Warning'' sections of labeling.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). They represent the agency's current thinking on this topic. They do not confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidances. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should identify clearly which guidance they are commenting on and should be identified with the docket number found in brackets in the heading of this document. The guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection(s) of information in the guidances are estimated in section ''VIII. Paperwork Reduction Act of 1995'' of the final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,'' published elsewhere in this issue of the **Federal Register**.

V. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–544 Filed 1–18–06; 10:29 am]

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Federal Register

Tuesday,
January 24, 2006

Part III

Department of the Treasury

Internal Revenue Service

26 CFR Parts 1, 301, and 602
Reporting for Widely Held Fixed Investment Trusts; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 301, and 602

[TD 9241]

RIN 1545–BA83

Reporting for Widely Held Fixed Investment Trusts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that define widely held fixed investment trusts, clarify the reporting obligations of the trustees and the middlemen connected with these trusts, and provide for communication of tax information to beneficial owners of trust interests. The regulations will affect trustees of, and middlemen holding interests on behalf of beneficial owners of trust interests with respect to, widely held fixed investment trusts.

DATES: *Effective Date:* These regulations are effective January 24, 2006.

Applicability Date: For dates of applicability of these regulations, see § 1.671–5(m).

FOR FURTHER INFORMATION CONTACT: Faith Colson, (202) 622–3060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been previously reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1540. Response to this collection of information is mandatory.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

The estimated annual burden per recordkeeper varies from 1 to 4 hours, depending on individual circumstances, with an estimated average of 2 hours. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to a collection of information must be retained as long as their contents might become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains amendments to 26 CFR parts 1, 301 and 602. On June 20, 2002, the Internal Revenue Service (IRS) and the Treasury Department withdrew proposed regulations (REG–209813–96) relating to the reporting requirements for widely held fixed investment trusts (WHFITs) previously published in the **Federal Register** (63 FR 43354) on August 13, 1998 (1998 Proposed Regulations) and published a new notice of proposed rulemaking (REG–106871–00) in the **Federal Register** (67 FR 41892) on June 20, 2002 (Reproposed Regulations). No public hearing was requested or held with respect to the Reproposed Regulations. Comments responding to the Reproposed Regulations were received. After consideration of the comments, the Reproposed Regulations, with certain revisions, are adopted as final regulations by this Treasury decision.

Section 301.7701–4(c) of the Procedure and Administration Regulations provides grantor trust treatment to an investment trust with a single class of ownership interests, representing undivided beneficial interests in the assets of the trust, if there is no power to vary the investment of the owners (a fixed investment trust). An investment trust with multiple classes of ownership interests, in which there is no power to vary the investment of the owners will also be treated as a grantor trust, if the trust is formed to facilitate direct investment in the assets of the trust and the existence of multiple classes is incidental to that purpose. Beneficial owners of trust interests are treated as grantors. See § 301.7701–4(c); see also Rev. Rul. 84–10, (1984–1 C.B. 155); Rev. Rul. 61–175, (1961–2 C.B. 128).

Trustees of fixed investment trusts frequently do not know the identities of the beneficial owners of the trust interests and are unable to communicate tax information directly to them because trust interests often are held in street name, *i.e.*, in the name of a middleman. The reproposed and final regulations provide rules that specifically require the sharing of tax information among trustees, middlemen, and beneficial owners of fixed investment trusts that meet the definition of a widely held fixed investment trust (WHFIT). (See section IA below.)

In general, the final regulations retain the structure of the Reproposed Regulations. Paragraph (c) of the reproposed and final regulations provides general reporting requirements for trustees to provide information to requesting persons, which include: (1) Middlemen, (2) beneficial owners who are brokers, (3) exempt recipients who hold their trust interests directly (and not through a middleman), (4) noncalendar-year beneficial owners who hold their trust interests directly, and (5) a representative or agent of any of the above. Paragraphs (d) and (e) of the reproposed and final regulations describe the responsibility of trustees and middlemen for information reporting to the IRS and beneficial owners. Paragraphs (f) and (g) of the reproposed and final regulations provide reporting safe harbors.

Explanation of Revisions to Reproposed Regulations and Summary of Comments

I. Definitions

A. Definition of a Widely Held Fixed Investment Trust and Classification as a Widely Held Mortgage Trust or a Non-Mortgage Widely Held Fixed Investment Trust

The Reproposed Regulations define a WHFIT as an arrangement classified as a trust under § 301.7701–4(c) in which at least one interest is held by a middleman, provided that the trust is classified as a United States person under section 7701(a)(30)(E). The final regulations retain this definition.

The Reproposed Regulations introduced the term *widely held mortgage trust* (WHMT) to describe a WHFIT, the assets of which are mortgages, amounts received on mortgages, and reasonably required reserve funds, as measured by value. The final regulations expand the definition of a WHMT, to provide that a WHFIT is also a WHMT if substantially all its assets also include trust interests in one or more WHMTs and regular interests in one or more real estate mortgage investment conduits (REMICs).

The final regulations also introduce a new term, *non-mortgage widely held fixed investment trust* (NMWHFIT), to clarify and distinguish the requirements and reporting safe-harbor for WHMTs from the requirements and reporting safe harbor applicable to other WHFITS. A NMWHFIT is any WHFIT that is not a WHMT.

B. Definition of a Mortgage

The Reproposed Regulations provide a reporting safe harbor for WHMTs that directly hold interests in mortgages; the safe harbor is not available to tiered arrangements. The IRS and the Treasury Department, after considering the comments received with respect to the Reproposed Regulations, have determined that the definition of a mortgage should be clarified in the final regulations to provide that an interest in a WHMT is not a mortgage under the regulations. Accordingly, the final regulations define a mortgage as an obligation that is principally secured by an interest in real property within the meaning of § 1.860G–2(a)(5) of the Income Tax Regulations, except that a mortgage does not include an interest in another WHMT or an interest in a mortgage held by another WHMT. The principal effect of this change is to clarify that, although a WHFIT investing in another WHMT is classified as a WHMT and is subject to the general reporting provisions that apply only to WHMTs, it is not eligible for the WHMT safe harbor reporting rules for the reasons discussed in section VI(B) below.

C. Definition of Trust Interest Holders, Beneficial Owners and Middleman

Under the Reproposed Regulations, a unit interest holder is defined as any person who holds a direct or indirect interest in a WHFIT at any time during the calendar year. The final regulations replace the term unit interest holder with two new terms: Trust interest holder (TIH) and beneficial owner. A TIH is any person who holds a direct or indirect interest in a WHFIT at any time during the calendar year. A beneficial owner is a TIH who holds a beneficial interest in a WHFIT. As in the Reproposed Regulations, in the final regulations, the term middleman refers to a TIH that holds a trust interest on behalf of, or for the account of, another person, or who otherwise acts in a capacity as an intermediary for the account of another person.

D. Definition of Item

The Reproposed Regulations use the term item without defining that term. Item as used in the final regulations refers broadly to an item of income, expense, or credit as well as any trust event (for example, the sale of an asset) or any characteristic or attribute of the above that affects the income, deductions, or credits reported by a beneficial owner in any taxable year that the beneficial owner holds a trust interest. Item also may refer to an individual item or to a group of items depending on whether the item must be reported individually under § 1.671–5(c)(1)(i) and (e)(1).

E. Definition of Start-Up Date

The Reproposed Regulations define the start-up date of a WHFIT as the date on which substantially all of the assets and the contracts for the purchase of assets are deposited with the trustee of the WHFIT. The Reproposed Regulations also define an asset to include an interest in a contract. Because the definition of an asset includes an interest in a contract, the definition of the start-up date in the Reproposed Regulations is revised in the final regulations to provide that the start-up date is the date on which substantially all of the assets are deposited with the trustee.

II. General Reporting and Record Retention Obligations

A. Requirement That the Trustee Provide Trust Information on a Calendar Year Basis

In general, the reproposed and final regulations require the trustee to provide information regarding the WHFIT to requesting persons. The Reproposed Regulations provide that the trustee could choose either a calendar month, calendar quarter, or half or full calendar year reporting period, provided that the information furnished by the trustee under the chosen reporting period allowed the recipient to determine the WHFIT items attributable to a particular beneficial owner with reasonable accuracy, regardless of the owner's taxable year or the period of time during the calendar year that the owner held the unit interest.

One commentator was concerned that if a trustee choose a reporting period shorter than a full calendar year, the trustee might also report trust information to middlemen more than once a year and because of this, middlemen would be required to process WHFIT information more than once a year. Another commentator was concerned that, if a trustee chose a reporting period shorter than a calendar year, the trustee could be required to report trust information more than once a year.

In response to these comments, the final regulations provide that, regardless of the period chosen by the trustee for calculating trust information, the trustee must provide the information required under these regulations on a calendar year basis. The trustee, of course, may provide additional trust information to requesting persons throughout the calendar year at the trustee's discretion. For example, if a trustee uses a monthly calculation period, the trustee must provide a single statement to requesting persons at the end of the year that contains the information required to be reported under these regulations for each month of the calendar year. In addition to the calendar year statement, the trustee may, but is not required to, provide additional statements to requesting persons during the calendar year.

To further clarify that a trustee may choose the period for calculating the information required to be reported under these regulations, but in all events must report that information to requesting persons on a calendar year basis, the final regulations refer to the period chosen by the trustee for calculating trust information as the calculation period rather than the reporting period.

B. Trustee's Burden To Retain Information and Supplemental Data

The Reproposed Regulations provide that, throughout the duration of the trust and for a period of five years following the termination of the trust, a trustee must retain: (1) A copy of the information required to be provided to requesting persons each year; and (2) any supplemental data necessary to establish that the information provided to requesting persons is correct and meets the requirements of paragraph (c) (supplemental data).

One commentator noted that some WHFITs, particularly WHMTs, may be in existence for up to 30 years and that the requirement in the Reproposed Regulations for a trustee to maintain the WHFIT's records for up to 35 years is overly burdensome. The commentator acknowledged that the IRS and investors may need to obtain WHFIT information from the trustee before the limitations period applicable to a beneficial owner's taxable year expires and suggested that the final regulations provide that a trustee only be required to retain information for a certain period after the close of the calendar year to which the information relates.

The IRS and the Treasury Department adopt this suggestion with respect to supplemental data. However, information with respect to each calendar year of the WHFIT may be required by the IRS and by beneficial owners in order to determine tax items of a beneficial owner (for example, market discount or basis) for the entire life of the WHFIT and for several years after its termination. For this reason, the final regulations continue to require the

trustee to retain a copy of the information required to be provided to requesting persons for the duration of the WHFIT and for at least five years after its termination. The IRS and the Treasury Department believe that this requirement is not overly burdensome because this information can be maintained electronically. The final regulations modify the requirement with respect to supplemental data by providing that trustees need only retain supplemental data for five years after the close of the calendar year to which the supplemental data relates.

C. Manner in Which WHFIT Information Is To Be Provided

The Reproposed Regulations provide that WHFIT information may be provided in any manner that enables a requesting person to determine, with reasonable accuracy, the WHFIT items that are attributable to a beneficial owner for the taxable year of that beneficial owner. The Reproposed Regulations further require that this information be furnished in a format that generally conforms to industry practice for the reporting of a particular item of income, deduction, or credit for the type of asset or assets held by the WHFIT.

One commentator suggested that, if the trustee is not providing trust information under a safe harbor, information could be shared more accurately and processed more efficiently if trustees were required to calculate and provide trust information on the basis of trust interests. The IRS and the Treasury Department do not agree that calculating and providing trust information on a per trust interest basis is always the best method for conveying information with respect to trust items that are not reported under the safe harbors. The requirement that the trustee provide information consistent with industry practice is intended to ensure that trustees provide WHFIT information in a format that can be processed by the systems used by the majority of middlemen. Accordingly, the final regulations do not adopt the suggestion.

One commentator also suggested that middlemen be permitted to furnish beneficial owners with information calculated on a trust interest basis rather than the amount of the item that is attributable to the beneficial owner. The final regulations permit a middleman or a trustee to furnish information calculated on a trust interest basis to a beneficial owner with respect to a trust item, if: (1) The amount of the item is not required to be provided to the IRS on an information return; and (2) the trustee calculates and provides information on the basis of a trust interest with respect to that trust item under paragraph (c) of the regulations.

D. Elimination of Separate General Reporting Rules for WHMTs

The Reproposed Regulations include separate reporting requirements for trustees and middlemen of WHMTs and trustees and middlemen of WHFITs other than WHMTs (*i.e.*, non-mortgage widely-held fixed investment trusts or NMWHFITs as defined in these final regulations), with respect to market discount, bond premium, and principal payments. The final regulations include general reporting requirements with respect to market discount, bond premium, and non pro-rata partial principal payment information that apply to all WHFITs. As under the Reproposed Regulations, the final regulations require WHMTs to provide market discount, bond premium, and non pro-rata partial principal payment information regardless of whether the WHMT meets one of the de minimis tests described in section III of the Preamble. Under the final regulations, however, NMWHFITs that meet the general de minimis test or the qualified NMWHFIT exception (also described in section III of the Preamble) are not required to provide information regarding bond premium and market discount.

E. Requirement That a Trustee Identify a Representative of the WHFIT and Identify the WHMT or as a NMWHFIT

The Reproposed Regulations require a trustee of a WHFIT to provide the name, address and telephone number of the WHFIT representative in a publication widely available to middlemen, in the trust's prospectus, or at the trustee's Internet website. The final regulations retain this requirement. Further, if the trustee provides trust information at an Internet website, the final regulations also require trustees, in addition to providing information regarding the WHFIT representative, to provide the address of the Internet website at which the trustee provides WHFIT information.

Two commentators were concerned that middlemen would not be able to identify a client's investment as an investment in a WHFIT and suggested that the IRS publish a directory or list of WHFITs that would include the name and CUSIP number of each WHFIT, along with the name, address and telephone number of the WHFIT's representative. Commentators noted that a publicly available directory or list would assist middlemen and brokers in identifying investment trusts as WHFITs and in locating the WHFIT's representatives.

In response to these comments, the final regulations require a trustee to identify the WHFIT as either a WHMT or a NMWHFIT when identifying the trust representative. Further, the IRS and the Treasury Department are studying whether a directory or list of WHFITs can be compiled by the IRS. The IRS and Treasury Department are concerned that such a directory is not currently feasible because of the large number of WHMTs. However, the IRS and Treasury request additional comments from middlemen regarding the type of WHFITs that should be included in any directory, the type of information needed by middlemen (especially, middlemen holding WHMT interests), and the format of a directory that would be most helpful. The IRS and Treasury Department also request comments from trustees regarding how the IRS could obtain the trust information needed for the directory from the trustees in the least burdensome manner for taxpayers as well as the Government.

III. Reporting of Asset Sales and Dispositions

A. General Information Reporting Requirements

Under the Reproposed Regulations, the trustee is required to provide information that would enable a requesting person to calculate the amount of trust sales proceeds attributable to a beneficial owner with respect to each sale or disposition of an asset by the trust. In addition, consistent with grantor trust treatment, unless a WHFIT meets the ''de minimis test,'' (discussed in III(B) of this Preamble), the trustee is required under the Reproposed Regulations to provide information that would enable a beneficial owner to allocate with reasonable accuracy a portion of its basis in its trust interest and to allocate a portion of its market discount or bond premium, if any, to each sale or disposition of an asset by the trust. The final regulations retain these general information reporting requirements for asset sales and dispositions. Although the requirements to provide market discount and bond premium information (discussed in section II(D) of this Preamble), are the same as those in the Reproposed Regulations, in the final regulations, for purposes of clarity, these requirements are provided separately from the requirement to provide information with respect to

sales and dispositions of assets by the trust.

The final regulations retain the exception from the general information reporting requirements for WHFITs that meet the general de minimis test. In addition, the final regulations provide an exception for WHMTs that meet a special de minimis test for WHMTs that directly hold interests in mortgages (the WHMT de minimis test is discussed in section III(E) of this Preamble). The final regulations also provide an exception from the general information reporting requirements for NMWHFITs that meet the qualified NMWHFIT exception, which is applicable only to NMWHFITs with a start up date that is on or before February 23, 2006.

B. Simplified Reporting for WHFITs That Meet the General WHFIT de minimis Test

For WHFITs that meet a de minimis test, the Reproposed Regulations substantially simplified reporting with respect to the sale or disposition of a trust asset from that required under the 1998 Proposed Regulations. These simplified rules balanced current industry practice with the need for beneficial owners to accurately report the tax consequences of ownership of a trust interest. Under the Reproposed Regulations, the WHFIT de minimis test is satisfied for the calendar year if the aggregate amount of trust sales proceeds for that calendar year is not more than five percent of the fair market value of the assets of the trust as of January 1 of that year (the general WHFIT de minimis test). The Reproposed Regulations define trust sales proceeds as the gross proceeds received by the WHFIT with respect to a sale or disposition of an asset by the WHFIT.

Under the Reproposed Regulations, if the trust meets the general WHFIT de minimis test, the trustee is excepted from the requirement to report information regarding basis, market discount and bond premium. The IRS and Treasury Department recognize that this method of reporting will likely result in some deferral of both gain and loss for investors, but have determined that, in cases where the WHFIT has de minimis sales and dispositions, the level of deferral is acceptable given the costs of fully accurate reporting of sales and dispositions. The final regulations retain this exception from the general requirement to provide basis, market discount and bond premium information for WHFITs that meet the general de minimis test.

C. Extension of Simplified Reporting to NMWHFITs That Meet the Qualified NMWHFIT Exception

Several commentators requested that the final regulations except WHFITs having a start-up date prior to the date of publication of these final regulations from the requirement to report basis, market discount, and bond premium information with respect to sales and dispositions. These commentators also requested that trustees and middlemen be permitted to report information regarding distributed trust sales proceeds rather than attributable trust sales proceeds.

To accommodate the industry's concerns regarding existing NMWHFITs, the final regulations add an exception for qualified NMWHFITs (the qualified NMWHFIT exception). The qualified NMWHFIT exception is met if a NMWHFIT has a start-up date that is on or before February 23, 2006 and the calendar year for which the trustee is reporting begins before January 1, 2011. NMWHFITs that meet the qualified NMWHFIT exception are excepted from the requirement that trustees and middlemen provide information regarding basis, market discount, and bond premium.

D. Distributed Trust Sales Proceeds May Be Reported by Trustees and Middlemen of Trusts Meeting the General de minimis Test or the Qualified NMWHFIT Exception

Several commentators noted that the requirement in the Reproposed Regulations that trustees of WHFITs other than WHMTs (NMWHFITs in these final regulations) report information to enable a requesting person to determine the amount of trust sales proceeds attributable to a beneficial owner would impose an undue burden. These commentators noted that, under current industry practice, trustees and middlemen of WHFITs other than WHMTs only report to the IRS and the beneficial owner the amount of trust sales proceeds distributed to the beneficial owner.

The IRS and Treasury Department have determined that if a NMWHFIT meets either the general WHFIT de minimis test for the calendar year or the qualified NMWHFIT exception, the purpose of reporting trust sales proceeds information to beneficial owners (e.g., to enable beneficial owners to adjust their basis in their trust interest to account for the sale or disposition of the trust asset) is met if the beneficial owner is given information regarding the amount of trust sales proceeds distributed to the beneficial owner. Accordingly, if a NMWHFIT meets either the general WHFIT de minimis test for the calendar year, or the qualified NMWHFIT exception, the final regulations require: (1) Trustees to report information that will enable middlemen to determine the amount of trust sales proceeds distributed to each beneficial owner during the calendar year; and (2) middlemen and trustees to report to the IRS and to each beneficial owner the amount of trust sales proceeds that are distributed to that beneficial owner.

E. Simplified Reporting for WHMTs That Meet the General de minimis Test or the Special WHMT de minimis Test

In addition to the general WHFIT de minimis test, the final regulations also provide a special WHMT de minimis test that applies to WHMTs that directly hold interests in mortgages (the special WHMT de minimis test). The special WHMT de minimis test is met if the trust sales proceeds received by the WHMT for the calendar year are not more than five percent of the aggregate outstanding principal balance of the WHMT (as defined in paragraph (g)(1)(iii)(D) of the final regulations) as of January 1 of that year. In applying the special WHMT de minimis test, amounts that result from the complete or partial payment of the outstanding principal balance of the mortgages held by the WHMT are not included in the amount of trust sales proceeds. A WHMT that holds interests in another WHMT or that holds interests in a REMIC may not use the special WHMT de minimis test, but may use the general WHFIT de minimis test (discussed in section III(B), above).

If a WHMT meets the special WHMT de minimis test or the general WHFIT de minimis test, trustees and middlemen are excepted from the general requirement to report information to enable a beneficial owner to allocate basis to a sale or disposition and are only required to report information regarding the trust sales proceeds that are attributable to a particular beneficial owner. If a WHMT does not meet a de miminis test, trustees and middlemen must report information to enable a beneficial owner to allocate basis to the sale or disposition as well as the trust sales proceeds that are attributable to the beneficial owner.

IV. Exception for Certain Equity Trusts From the Requirement That Trustees and Middlemen Report Information To Enable a Requesting Person To Determine the Income That Is Attributable to a Redeeming or Selling Beneficial Owner Up to the Date of Redemption or Sale

The Reproposed Regulations require trustees and middlemen to report information to enable requesting persons to determine the income of the WHFIT attributable to a selling, purchasing, or redeeming beneficial owner for the portion of the calendar year that the beneficial owner held its trust interest. Commentators objected to this requirement for WHFITs if substantially all the income of the WHFIT is comprised of dividends (equity trusts). These commentators noted that although trustees and middlemen report interest income earned by the WHFIT up to the date of redemption or sale of a trust interest, providing this information with respect to dividend income is inconsistent with long-standing WHFIT industry reporting practice. Currently there is no mechanism in place for communicating this information between trustees and middlemen of equity trusts. Under current industry practice, the entire amount paid to a beneficial owner who sells or redeems an interest in an equity trust, including the amount paid for undistributed dividends held by the trust at the time of the sale or redemption, is reported to the IRS and to the beneficial owner as gross proceeds. As a result, a selling or redeeming beneficial owner may report the ordinary dividend income portion of the payment as a capital gain. The purchasing beneficial owner also receives incorrect income information that may lead the purchasing beneficial owner to overstate its dividend income. Commentators objected to expending resources for the development and testing of new tax reporting systems to accurately report dividend income to selling, purchasing, and redeeming beneficial owners, especially with respect to existing equity trusts.

Commentators acknowledge, however, that the net asset value of an equity trust, including the cash held for distribution, generally is calculated on a daily basis. Because in the final regulations, the cash held for distribution is a key component in calculating the amount of income attributable to a selling, purchasing, or redeeming beneficial owner under the safe harbor for NMWHFITs, the final regulations retain the general requirement that trustees and middlemen provide information to determine the trust income that should be attributed to a redeeming, selling, or purchasing beneficial owner.

The IRS and the Treasury Department recognize, however, that if an equity trust frequently distributes its income, the trust is not likely to accumulate significant undistributed dividend income. In such a case, the increased accuracy that results from providing beneficial owners with accurate income information up to the date of sale or redemption does not warrant the burden of compiling and reporting this information. Accordingly, under the final regulations, trustees or middlemen of equity trusts that are required by their governing documents to distribute all cash (less reasonably required reserve funds) held by the NMWHFIT at least monthly need not provide information regarding the income that is attributable to a redeeming, selling, or purchasing beneficial owner up to the date of sale or redemption. The final regulations also except trustees and middlemen of an equity trust that meets the qualified NMWHFIT exception (described in section III of this Preamble) from the requirement that trustees and middlemen provide information regarding the income that is attributable to a redeeming, selling, or purchasing beneficial owner up to the date of sale or redemption.

V. Safe Harbor Reporting for WHFITs

A. The Safe Harbors Must Be Used Consistently

Under the Reproposed Regulations, a trustee of a WHFIT can decide whether or not to use the safe harbor reporting practices on a year-by-year basis. The IRS and the Treasury Department have concluded, however, that middlemen and beneficial owners should receive WHFIT information that is calculated consistently from one calendar year to the next because, assuming beneficial owners report trust items consistent with the WHFIT information provided to them, a trustee's change in reporting could result in changes in the timing that may impact beneficial owners. Further, allowing trustees to report under the safe harbor one year and not the next, likely would confuse and burden the middlemen and beneficial owners that must process WHFIT information. Accordingly, the final regulations require trustees that choose to use the safe harbor to report under the safe harbor for the life of the WHFIT. WHFITs that have a start-up date prior to January 1, 2007 may choose to report under the safe harbor provided the trustee begins to report according to the safe harbor requirements on or before January 1, 2007 and does so for the life of the WHFIT.

Under the Reproposed Regulations and the final regulations, a WHMT must meet the eligibility requirements of § 1.671–5(g)(1)(ii) and report consistently with the safe harbor reporting rules to be deemed to have met its reporting requirements under paragraph (c) of the regulations with respect to the trust items described in the safe harbor. The final regulations eliminate two of the eligibility requirements in the Reproposed Regulations that are inconsistent with the rule that the safe harbor must be used for the life of the WHMT.

B. Request for Comments Regarding the Need for Safe Harbors for NMWHFITs That Are Outside the Safe Harbor in the Final Regulations

The Reproposed Regulations include safe harbor reporting rules available to WHFITs other than WHMTs (*i.e.*, NMWHFITs). If the trustee of a WHFIT other than a WHMT reports consistently with the safe harbor, the trustee is deemed to have met the requirements of paragraph (c)(1) of the Reproposed Regulations. Those safe harbor reporting rules were developed in response to comments received on the 1998 Proposed Regulations describing the current reporting practices of WHFITs that primarily receive dividend and interest income.

Upon reconsideration of those safe harbor reporting rules and the various types of NMWHFITs, the IRS and the Treasury Department recognize that the type of information reported under those reporting rules is only relevant to NMWHFITs that hold stock and debt instruments and that information reported under the safe harbor probably would not be useful to middlemen and beneficial owners of NMWHFITs that hold other types of assets. As a result, the IRS and Treasury concluded that safe harbor treatment should only be available to NMWHFITs for which the safe harbors were designed (*e.g.*, NMWHFITs that hold stock and debt instruments) and that other safe harbor reporting rules should govern NMWHFITs that are outside the safe harbor. Accordingly, in the final regulations only NMWHFITs substantially all the income of which is comprised of dividends (as defined in section 6042(b) and the regulations thereunder) or interest (as defined in section 6049(b) and the regulations thereunder) that report as provided in the NMWHFIT safe harbor will be deemed to have met the requirements of paragraph (c)(1) of the final regulations.

The IRS and the Treasury Department are considering providing additional safe harbor reporting rules for NMWHFITs that are not under the NMWHFIT safe harbor in the final regulations and encourage trustees and middlemen to submit comments regarding NMWHFITs for which further reporting safe harbors should be provided, including information regarding current industry reporting practice for NMWHFITs that do not qualify for the NMWHIFIT safe harbor in the final regulations.

C. Safe Harbor Reporting for WHMTs

1. Reporting Sales and Dispositions Under the WHMT Safe Harbor

The 1998 Proposed Regulations did not allow trustees and middlemen to aggregate sales and dispositions of trust assets, even fungible trust assets, for reporting purposes. In response to comments on the 1998 Proposed Regulations, as well as the addition of section 1272(a)(6)(C)(iii) to the Code in 1997, the Reproposed Regulations permit aggregate reporting for sales and dispositions and principal receipts for WHMTs eligible to report under the WHMT safe harbor. Under the WHMT safe harbor, a trustee is permitted to combine, for reporting purposes, amounts received as trust sales proceeds from the sale or disposition of some mortgages (including principal receipts that completely retire a mortgage) with non pro-rata partial principal payments from other mortgages. Thus, the safe harbor permits trustees and middlemen to report trust information as if the WHMT, in effect, held only one mortgage, and to report the aggregate of trust sales proceeds and non pro-rata partial principal payments as though the trustee had received a non pro-rata partial principal payment on that mortgage.

The WHMT safe harbor in the Reproposed Regulations is only available to WHMTs that met the requirements of § 1.671–5(g)(1)(ii) of those regulations. Commentators requested that the final regulations provide that trustees of all WHMTs, not just those meeting the eligibility requirements of § 1.671–5(g)(1)(ii), be allowed to apply this treatment for reporting purposes. The commentators suggested that reporting sales and dispositions separately from principal payments is unnecessary because receipt by the trust of trust sales proceeds and receipt of principal payments have identical tax consequences for a beneficial owner.

Under Rev. Rul. 84–10 (1984–1 C.B. 155), a beneficial owner of a WHMT is treated for federal income tax purposes as having a proportionate share of equitable ownership in each of the mortgages of the WHMT. If a taxpayer owns mortgages outright and not in trust, the taxpayer does not report mortgage sales proceeds or the complete prepayment of a mortgage in the same manner as the receipt of a non pro-rata partial principal payment. That is, a taxpayer that owns two mortgages does not combine the sale of one mortgage with the receipt of non pro-rata partial principal payments from the other mortgage for purposes of calculating the taxpayer's federal income tax liability. For this reason and the reasons discussed in section V(B)(3) of this Preamble, the IRS and Treasury Department do not adopt the commentators' request.

2. Requirement That Trustees Use a Prepayment Assumption When Providing Market Discount and OID Information Under the WHMT Safe Harbor

The Reproposed Regulations require trustees and middlemen of all WHMTs to report information to enable beneficial owners to calculate market discount in any reasonable manner that is consistent with section 1276(a)(3). Regulations have not been issued under the market discount provisions of the Code (sections 1276 to 1278). The preamble to the Reproposed Regulations notes that, in the absence of regulations governing accrual of market discount, guidance regarding the accrual of market discount with respect to the partial payment of a debt instrument is provided in the conference report (see H.R. Rep. No. 841, 99th Cong., 2nd Sess., at II–842 (1986)) accompanying the amendment that enacted section 1276(a)(3) (see section 1803(a)(13)(A) of the Tax Reform Act of 1986, Public Law 99–514, 100 Stat. 2085) (the Conference Report). Consistent with Congressional intent expressed in the Conference Report indicating that holders must report market discount in the absence of regulations, the Reproposed Regulations impose a general requirement that trustees and middlemen of WHMTs report market discount information.

The WHMT safe harbor provision for reporting market discount information in the Reproposed Regulations is based on the Conference Report. Under that safe harbor, trustees report market discount by providing one market discount fraction for the WHMT that is the ratio of, either: (1) The OID accrued during the month to the total remaining OID as of the beginning of the month; or (2) the interest paid during the month to the remaining interest payable on the mortgages held by the WHMT as of the beginning of the month. The Reproposed Regulations require trustees to utilize a method that takes into account the prepayment assumption used in pricing the original issue of trust interests. The Reproposed Regulations also include a WHMT safe harbor provision for OID information that required the use of the same prepayment assumption.

Commentators reported that they assumed that the Reproposed Regulations permit trustees to use the safe harbor for reporting only sales and dispositions and the receipt of principal payments and to ignore other trust items, such as market discount and OID, when reporting under the safe harbor.

The WHMT safe harbor in the final regulations permits trustees and middlemen of WHMTs that meet the requirements of § 1.671–5(g)(1)(ii), to aggregate the trust sales proceeds received from sales and dispositions of some mortgages with non pro-rata partial principal payments on other mortgages, but the safe harbor also requires trustees and middlemen to report market discount and OID information consistent with section 1272(a)(6). Safe harbor treatment is available to WHMTs that meet the requirements of § 1.671–5(g)(1)(ii) because the IRS and the Treasury Department have determined that, for those WHMTs, if market discount and OID are reported as provided in the safe harbor, mortgage-by-mortgage reporting with respect to sales and dispositions and principal payments is unnecessary. Accordingly, the final regulations clarify that, for a trustee to be deemed to have met the requirements of paragraph (c)(1) of the regulations, the trustee must report all items identified in the WHMT safe harbor consistent with the WHMT safe harbor.

3. Reporting for WHMTs That Are Outside the Safe Harbor

Some commentators may view the Conference Report as providing authority to report market discount information using a single composite fraction, regardless of whether the trustee is permitted to, and does in fact, report under the WHMT safe harbor. The IRS and the Treasury Department disagree with the commentators' reading of the Conference Report as applied to WHMTs. The Conference Report simply provides that, until such time as the Treasury Department issues regulations regarding the computation of the accrual of market discount, holders may elect to accrue market discount using either a constant interest method or a market discount fraction.

The Conference Report may implicitly discuss aggregate reporting in that it states that, in the case of debt instruments that would be subject to the OID rules contained in section 1272(a)(6) (without regard to whether the debt instruments have OID), the same prepayment assumption that would be made in computing OID would be made in computing the accrual of market discount (whether or not the taxpayer elects to accrue market discount on the basis of a constant interest rate). Section 1272(a)(6)(C)(iii) provides that section 1272(a)(6) applies to any pool of debt instruments, the yield on which may be affected by reason of prepayments. However, no guidance has been issued regarding the application of section 1272(a)(6)(C)(iii). Until guidance is issued under section 1272(a)(6)(C)(iii), the IRS and Treasury Department believe that it is appropriate to provide safe harbor treatment only for trustees of relatively straight forward arrangements who report information consistent with the application of section 1272(a)(6) as provided by the safe harbor reporting rules.

4. Reporting Bond Premium Under the WHMT Safe Harbor

The Reproposed Regulations include a general requirement that trustees and middlemen of all WHMTs report information to enable beneficial owners to determine the amount of amortizable bond premium, if any, in any manner that is reasonably consistent with section 171. The Reproposed Regulations reserve the portion of the WHMT safe harbor on reporting information regarding bond premium. None of the comments on the Reproposed Regulations specifically addressed bond premium issues. Accordingly, the final regulations continue to reserve guidance on the issue while the IRS and the Treasury Department study how bond premium information is to be appropriately reported for WHMTs. The IRS and the Treasury Department welcome comments on this issue. Until safe harbor reporting rules are provided for bond premium, a trustee will not be penalized if the trustee reports information that enables a beneficial owner to determine, in any manner reasonably consistent with section 171, the amount of the beneficial owner's amortizable bond premium, if any, for the calendar year.

VI. Application of Reporting Rules to Foreign Fixed Investment Trusts

A fixed investment trust that is not classified as a United States person is not a WHFIT under the Reproposed Regulations or the final regulations. Nothing in the Reproposed Regulations or these final regulations alters the application of section 6048 to United States investors in a foreign fixed investment trust. The preamble to the Reproposed Regulations notes that the IRS and the Treasury Department continue to study how to facilitate the application of section 6048 rules to foreign fixed investment trusts and requested comments on this issue, including how forms 3520 and 3520A could be adapted for use with foreign fixed investment trusts.

Commentators suggested that many beneficial owners of interests in a foreign fixed investment trust cannot comply with the reporting requirements of section 6048 because they cannot obtain the necessary information from the trustee. These commentators suggested that, rather than adapting Forms 3520 and 3520A to foreign fixed investment trusts, the IRS and the Treasury Department should permit certain foreign fixed investment trusts to report pursuant to the reporting rules in these regulations. The commentators also suggested that the final regulations provide that, if a foreign fixed investment trust reports pursuant to these reporting rules, United States investors in the trust be excepted from the reporting rules in section 6048. The IRS and the Treasury Department intend to provide guidance in the area of foreign trust reporting and will consider whether any of the suggested approaches for WHFITs are more appropriate in this context.

VII. Effective Date of Final Regulations and Applicability to Existing WHFITs

The Reproposed Regulations provide that the reporting rules were to be applicable beginning January 1, 2004. Most commentators requested that the applicability date be delayed until January 1, 2005, to enable trustees and middlemen to change their reporting systems to comply with the new reporting rules. To ensure that there is sufficient time to comply with the reporting requirements, the final regulations provide that these regulations are effective January 1, 2007. Accordingly, beginning with the 2007 calendar year, trustees must report trust information in accordance with paragraph (c) of the final regulations. Trustees and middlemen must file Forms 1099 with the IRS and furnish tax information statements to beneficial owners that meet the requirements of paragraphs (d) and (e) of the final regulations with respect to the 2007 calendar year and all subsequent years.

Regarding the applicability of these reporting rules to existing WHFITs, one commentator requested that the final regulations except all WHFITs in existence as of the effective date of the final regulations from the new reporting rules. Other commentators requested that WHFITs in existence as of the effective date of the final regulations be excepted from specific provisions. The final regulations apply to all WHFITs, including those in existence as of the effective date. However, in response to the comments, the final regulations except certain NMWHFITs that have a start-up date on or before February 23, 2006 from specific reporting requirements regarding market discount, bond premium, sales and dispositions, redemptions, and sales of trust interests until January 1, 2011. The details of these exceptions have been discussed in sections IID, III, and IV of this preamble.

Special Analysis

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the regulations generally clarify existing reporting obligations and are expected, for the most part, to have minimal impact on industry practice, and to not have a significant economic impact on entities subject to the regulations. Further, the reporting burdens in these regulations will fall primarily on large brokerage firms, large banks, and other large entities acting as trustees or middlemen, most of which are not small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. chapter 6). Thus, a substantial number of small entities are not expected to be affected. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the proposed and the Reproposed Regulations preceding these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Faith Colson of the Office of Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of the Amendments to the Regulations

■ Accordingly, 26 CFR parts 1, 301, and 602 are amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.671–4 is amended by revising paragraph (a) to read as follows:

§ 1.671–4 Method of reporting.

(a) *Portion of trust treated as owned by the grantor or another person.* Except as otherwise provided in paragraph (b) of this section and § 1.671–5, items of income, deduction, and credit attributable to any portion of a trust that, under the provisions of subpart E (section 671 and following), part I, subchapter J, chapter 1 of the Internal Revenue Code, is treated as owned by the grantor or another person, are not reported by the trust on Form 1041, ''U.S. Income Tax Return for Estates and Trusts,'' but are shown on a separate statement to be attached to that form. Section 1.671–5 provides special reporting rules for widely held fixed investment trusts. Section 301.7701–4(e)(2) of this chapter provides guidance regarding the application of the reporting rules in this paragraph (a) to an environmental remediation trust.

* * * * *

■ **Par. 3.** Section 1.671–5 is added to read as follows:

§ 1.671–5 Reporting for widely held fixed investment trusts.

(a) *Table of contents.* This table of contents lists the major paragraph headings for this section.

(a) Table of contents.
(b) Definitions.
(c) Trustee's obligation to report information.
(1) In general.
(i) Calculation.
(ii) Calculation period.
(iii) Accounting method.
(iv) Gross income requirement.
(2) Information to be reported by all WHFITs.
(i) Trust identification and calculation period chosen.
(ii) Items of income, expense, and credit.
(iii) Non pro-rata partial principal payments.
(iv) Asset sales and dispositions.
(v) Redemptions and sales of WHFIT interests.
(vi) Information regarding bond premium.
(vii) Information regarding market discount.
(viii) Other information.
(3) Identifying the representative who will provide trust information.
(4) Time and manner of providing information.
(i) Time.
(ii) Manner.
(iii) Inclusion of information with respect to all calculation periods.
(5) Requesting information from a WHFIT.
(i) In general.
(ii) Manner of requesting information.
(iii) Period of time during which a requesting person may request WHFIT information.
(6) Trustee's requirement to retain records.
(d) Form 1099 requirement for trustees and middlemen.
(1) Obligation to file Form 1099 with the IRS.
(i) In general.
(ii) Forms 1099 not required for exempt recipients.
(iii) Reporting and withholding with respect to foreign persons.
(2) Information to be reported.
(i) Determining amounts to be provided on Forms 1099.
(ii) Information to be provided on Forms 1099.
(3) Time and manner of filing Forms 1099.
(i) Time and place.
(ii) Reporting trust sales proceeds, redemption asset proceeds, redemption proceeds, sales asset proceeds, sales proceeds, and non pro-rata partial principal payments.
(e) Requirement to furnish a written tax information statement to the TIH.
(1) In general.
(2) Information required.
(i) WHFIT information.
(ii) Identification of the person furnishing the statement.
(iii) Items of income, expense, and credit.
(iv) Non pro-rata partial principal payments.
(v) Asset sales and dispositions.
(vi) Redemption or sale of a trust interest.
(vii) Information regarding market discount and bond premium.
(viii) Other information.
(ix) Required statement.
(3) Due date and other requirements.
(4) Requirement to retain records.
(f) Safe harbor for providing information for certain NMWHFITs.
(1) Safe harbor for trustee reporting of NMWHFIT information.
(i) In general.
(ii) Reporting NMWHFIT income and expenses.
(iii) Reporting non pro-rata partial principal payments under the safe harbor.
(iv) Reporting sales and dispositions of NMWHFIT assets under the safe harbor.
(v) Reporting redemptions under the safe harbor.
(vi) Reporting the sale of a trust interest under the safe harbor.
(vii) Reporting OID information under the safe harbor.
(viii) Reporting market discount information under the safe harbor.
(ix) Reporting bond premium information under the safe harbor.
(x) Reporting additional information.
(2) Use of information provided by trustees under the safe harbor for NMWHFITs.
(i) In general.
(ii) Determining NMWHFIT income and expenses under the safe harbor.
(iii) Reporting non pro-rata partial principal payments under the safe harbor.
(iv) Reporting sales and dispositions of NMWHFIT assets under the safe harbor.
(v) Reporting redemptions under the safe harbor.
(vi) Reporting sales of trust interests under the safe harbor.
(vii) Reporting OID information under the safe harbor.
(viii) Reporting market discount information under the safe harbor.
(ix) Reporting bond premium information under the safe harbor.
(3) Example of the use of the safe harbor for NMWHFITs.
(i) Facts.
(ii) Trustee reporting.
(iii) Brokers' use of information provided by Trustee.
(g) Safe Harbor for certain WHMTs.
(1) Safe harbor for trustees of certain WHMTs for reporting information.
(i) In general.
(ii) Requirements.
(iii) Reporting WHMT income, expenses, non pro-rata partial principal payments, and sales and dispositions under the safe harbor.
(iv) Reporting OID information under the safe harbor.
(v) Reporting market discount information under the safe harbor.
(vi) Reporting bond premium information under the safe harbor.
(2) Use of information provided by a trustee under the safe harbor.
(i) In general.
(ii) Reporting WHMT income, expenses, non pro-rata partial principal payments, and sales and dispositions under the safe harbor.
(iii) Reporting OID information under the safe harbor.
(iv) Requirement to provide market discount information under the safe harbor.
(v) Requirement to provide bond premium information under the safe harbor.
(3) Example of safe harbor in paragraph (g)(1) of this section.
(i) Facts.
(ii) Trustee reporting.
(iii) Broker's use of the information provided by Trustee.
(h) Requirement that middlemen furnish information to beneficial owners that are exempt recipients and non calendar year beneficial owners.
(1) In general.
(2) Time for providing information.
(3) Manner of providing information.
(4) Clearing organization.

(i) Reserved.
(j) Coordination with other information reporting rules.
(k) Backup withholding requirements.
(l) Penalties for failure to comply.
(m) Effective date.

(b) *Definitions.* Solely for purposes of this section:

(1) An *asset* includes any real or personal, tangible or intangible property held by the trust, including an interest in a contract.

(2) An *affected expense* is an expense described in § 1.67–2T(i)(1).

(3) A *beneficial owner* is a trust interest holder (TIH) (as defined in paragraph (b)(20) of this section) that holds a beneficial interest in a widely held fixed investment trust (WHFIT) (as defined in paragraph (b)(22) of this section.)

(4) The *calculation period* is the period the trustee chooses under paragraph (c)(1)(ii) of this section for calculating the trust information required to be provided under paragraph (c) of this section.

(5) The *cash held for distribution* is the amount of cash (other than trust sales proceeds) that would be payable to TIHs if the amount of a distribution were required to be determined as of the date in question.

(6) A *clean-up call* is the redemption of all trust interests in termination of the WHFIT when the administrative costs of the WHFIT outweigh the benefits of maintaining the WHFIT.

(7) An *exempt recipient* is—

(i) Any person described in § 1.6049–4(c)(1)(ii);

(ii) A middleman (as defined in paragraph (b)(10) of this section);

(iii) A real estate mortgage investment conduit (as defined in section 860(D)(a)) (REMIC);

(iv) A WHFIT; or

(v) A trust or an estate for which the trustee or middleman of the WHFIT is also required to file a Form 1041, ''U.S. Income Tax Return for Estates and Trusts,'' in its capacity as a fiduciary of that trust or estate.

(8) An *in-kind redemption* is a redemption in which a beneficial owner receives a pro-rata share of each of the assets of the WHFIT that the beneficial owner is deemed to own under section 671.

(9) An *item* refers to an item of income, expense, or credit as well as any trust event (for example, the sale of an asset) or any characteristic or attribute of the trust that affects the income, deductions, and credits reported by a beneficial owner in any taxable year that the beneficial owner holds an interest in the trust. An item may refer to an individual item or a group of items depending on whether the item must be reported separately under paragraphs (c)(1)(i) and (e)(1) of this section.

(10) A *middleman* is any TIH, other than a qualified intermediary as defined in § 1.1031(k)–1(g), who, at any time during the calendar year, holds an interest in a WHFIT on behalf of, or for the account of, another TIH, or who otherwise acts in a capacity as an intermediary for the account of another person. A middleman includes, but is not limited to—

(i) A custodian of a person's account, such as a bank, financial institution, or brokerage firm acting as custodian of an account;

(ii) A nominee;

(iii) A joint owner of an account or instrument other than—

(A) A joint owner who is the spouse of the other owner; and

(B) A joint owner who is the beneficial owner and whose name appears on the Form 1099 filed with respect to the trust interest under paragraph (d) of this section; and

(iv) A broker (as defined in section 6045(c)(1) and § 1.6045–1(a)(1)), holding an interest for a customer in street name.

(11) A *mortgage* is an obligation that is principally secured by an interest in real property within the meaning of § 1.860G–2(a)(5), except that a mortgage does not include an interest in another WHFIT or mortgages held by another WHFIT.

(12) A *non-mortgage widely held fixed investment trust* (NMWHFIT) is a WHFIT other than a widely held mortgage trust (as defined in paragraph (b)(23) of this section).

(13) A *non pro-rata partial principal payment* is any partial payment of principal received on a debt instrument which does not retire the debt instrument and which is not a pro-rata prepayment described in § 1.1275–2(f)(2).

(14) The *redemption asset proceeds* equal the redemption proceeds (as defined in paragraph (b)(15) of this section) less the cash held for distribution with respect to the redeemed trust interest.

(15) The *redemption proceeds* equal the total amount paid to a redeeming TIH as the result of a redemption of a trust interest.

(16) A *requesting person* is—

(i) A middleman;

(ii) A beneficial owner who is a broker;

(iii) A beneficial owner who is an exempt recipient who holds a trust interest directly and not through a middleman;

(iv) A noncalendar-year beneficial owner who holds a trust interest directly and not through a middleman; or

(v) A representative or agent of a person specified in this paragraph (b)(16).

(17) The *sales asset proceeds* equal the sales proceeds (as defined in paragraph (b)(18) of this section) less the cash held for distribution with respect to the sold trust interest at the time of the sale.

(18) The *sales proceeds* equal the total amount paid to a selling TIH in consideration for the sale of a trust interest.

(19) The *start-up date* is the date on which substantially all of the assets have been deposited with the trustee of the WHFIT.

(20) A *trust interest holder* (TIH) is any person who holds a direct or indirect interest, including a beneficial interest, in a WHFIT at any time during the calendar year.

(21) *Trust sales proceeds* equal the amount paid to a WHFIT for the sale or disposition of an asset held by the WHFIT, including principal payments received by the WHFIT that completely retire a debt instrument (other than a final scheduled principal payment) and pro-rata partial principal prepayments described under § 1.1275–2(f)(2). Trust sales proceeds do not include amounts paid for any interest income that would be required to be reported under § 1.6045–(d)(3).

(22) A *widely held fixed investment trust* (WHFIT) is an arrangement classified as a trust under § 301.7701–4(c) of this chapter, provided that—

(i) The trust is a United States person under section 7701(a)(30)(E);

(ii) The beneficial owners of the trust are treated as owners under subpart E, part I, subchapter J, chapter 1 of the Internal Revenue Code; and

(iii) At least one interest in the trust is held by a middleman.

(23) A *widely held mortgage trust* (WHMT) is a WHFIT, the assets of which consist only of one or more of the following—

(i) Mortgages;

(ii) Regular interests in a REMIC;

(iii) Interests in another WHMT;

(iv) Reasonably required reserve funds;

(v) Amounts received on the assets described in paragraphs (b)(23)(i), (ii), (iii), and (iv) of this section pending distribution to TIHs; and

(vi) During a brief initial funding period, cash and short-term contracts for the purchase of the assets described in paragraphs (b)(23)(i), (ii), and (iii).

(c) *Trustee's obligation to report information*—(1) *In general.* Upon the

request of a requesting person (as defined in paragraph (b)(16) of this section), a trustee of a WHFIT must report the information described in paragraph (c)(2) of this section to the requesting person. The trustee must determine such information in accordance with the following rules—

(i) *Calculation.* WHFIT information may be calculated in any manner that enables a requesting person to determine with reasonable accuracy the WHFIT items described in paragraph (c)(2) of this section that are attributable (or, if permitted under paragraphs (c)(2)(iv)(B) or (f)(2)(iii) of this section, distributed) to a beneficial owner for the taxable year of that owner. The manner of calculation must generally conform with industry practice for calculating the WHFIT items described in paragraph (c)(2) of this section for the type of asset or assets held by the WHFIT, and must enable a requesting person to separately state any WHFIT item that, if taken into account separately by a beneficial owner, would result in an income tax liability different from that which would result if the owner did not take the item into account separately.

(ii) *Calculation period*—WHFIT information may be calculated on the basis of a calendar month, calendar quarter, or half or full calendar year, provided that a trustee uses the same calculation period for the life of the WHFIT and the information provided by the trustee meets the requirements of paragraph (c)(1)(i) of this section. Regardless of the calculation period chosen by the trustee, the trustee must provide information requested by a requesting person under paragraph (c)(5) on a calendar year basis. The trustee may provide additional information to requesting persons throughout the calendar year at the trustee's discretion.

(iii) *Accounting method*—(A) *General rule.* WHFIT information must be calculated and reported using the cash receipts and disbursements method of accounting unless another method is required by the Internal Revenue Code or regulations with respect to a specific trust item. Accordingly, a trustee must provide information necessary for TIHs to comply with the rules of subtitle A, chapter 1, subchapter P, part V, subpart A of the Internal Revenue Code, which require the inclusion of accrued amounts with respect to OID, and section 860B(b), which requires the inclusion of accrued amounts with respect to a REMIC regular interest.

(B) *Exception for WHFITs marketed predominantly to taxpayers on the accrual method.* If the trustee or the trust's sponsor knows or reasonably should know that a WHFIT is marketed primarily to accrual method TIHs and the WHFIT holds assets for which the timing of the recognition of income is materially affected by the use of the accrual method of accounting, the trustee must calculate and report trust information using the accrual method of accounting.

(iv) *Gross income requirement.* The amount of income required to be reported by the trustee is the gross income (as defined in section 61) generated by the WHFIT's assets. Thus, in the case of a WHFIT that receives a payment of income from which an expense (or expenses) has been deducted, the trustee, in calculating the income to be reported under paragraph (c)(2)(ii) of this section, must report the income earned on the trusts assets unreduced by the deducted expense or expenses and separately report the deducted expense or expenses. See paragraph (c)(2)(iv) of this section regarding reporting with respect to sales and dispositions.

(2) *Information to be reported by all WHFITs.* With respect to all WHFITs—

(i) *Trust identification and calculation period chosen.* The trustee must report information identifying the WHFIT, including—

(A) The name of the WHFIT;

(B)The employer identification number of the WHFIT;

(C) The name and address of the trustee;

(D) The Committee on Uniform Security Identification Procedure (CUSIP) number, account number, serial number, or other identifying number of the WHFIT;

(E) The classification of the WHFIT as either a WHMT or NMWHFIT; and

(F) The calculation period used by the trustee.

(ii) *Items of income, expense, and credit.* The trustee must report information detailing—

(A) All items of gross income (including OID);

(B) All items of expense (including affected expenses); and

(C) All items of credit.

(iii) *Non pro-rata partial principal payments.* The trustee must report information detailing non pro-rata partial principal payments (as defined in paragraph (b)(13) of this section) received by the WHFIT.

(iv) *Asset sales and dispositions.* The trustee must report information regarding sales and dispositions of WHFIT assets as required in this paragraph (c)(2)(iv). For purposes of this paragraph (c)(2)(iv), a payment (other than a final scheduled payment) that completely retires a debt instrument (including a mortgage held by a WHMT) or a pro-rata prepayment on a debt instrument (see § 1.1275–2(f)(2)) held by a WHFIT must be reported as a full or partial sale or disposition of the debt instrument.

(A) *General rule.* Except as provided in paragraph (c)(2)(iv)(B) (regarding the exception for certain NMWHFITs) or (c)(2)(iv)(C) (regarding the exception for certain WHMTs) of this section, the trustee must report with respect to each sale or disposition of a WHFIT asset—

(*1*) The date of each sale or disposition;

(*2*) Information that enables a requesting person to determine the amount of trust sales proceeds (as defined in paragraph (b)(21) of this section) attributable to a beneficial owner as a result of each sale or disposition; and

(*3*) Information that enables a beneficial owner to allocate, with reasonable accuracy, a portion of the owner's basis in its trust interest to each sale or disposition.

(B) *Exception for certain NMWHFITs.* If a NMWHFIT meets either the general WHFIT de minimis test of paragraph (c)(2)(iv)(D)(*1*) of this section for a calendar year, or the qualified NMWHFIT exception of paragraph (c)(2)(iv)(E) of this section, the trustee is not required to report under paragraph (c)(2)(iv)(A) of this section. Instead, the trustee must report sufficient information to enable a requesting person to determine the amount of trust sales proceeds distributed to a beneficial owner during the calendar year with respect to each sale or disposition of a trust asset. The trustee also must provide requesting persons with a statement that the NMWHFIT is permitted to report under this paragraph (c)(2)(iv)(B).

(C) *Exception for certain WHMTs.* If a WHMT meets either of the de minimis tests of paragraph (c)(2)(iv)(D) of this section for the calendar year, the trustee is not required to report under paragraph (c)(2)(iv)(A) of this section. Instead, the trustee must report information to enable a requesting person to determine the amount of trust sales proceeds attributable to a beneficial owner as a result of the sale or disposition. The trustee also must provide requesting persons with a statement that the WHMT is permitted to report under this paragraph (c)(2)(iv)(C).

(D) *De minimis tests*—(*1*) *General WHFIT de minimis test.* The general WHFIT de minimis test applies to a NMWHFIT or to a WHMT that does not meet the requirements for the special

WHMT de minimis test in paragraph (c)(2)(iv)(D)(*2*) of this section. The general WHFIT de minimis test is satisfied if trust sales proceeds for the calendar year are not more than five percent of the aggregate fair market value of all assets held by the trust as of the later of January 1st of that year or the trust's start-up date (as defined in paragraph (b)(19) of this section).

(*2*) *Special WHMT de minimis test.* A WHMT that meets the asset requirement of paragraph (g)(1)(ii)(D) of this section satisfies the special WHMT de minimis test in this paragraph (c)(2)(iv)(D)(*2*) if trust sales proceeds for the calendar year are not more than five percent of the aggregate outstanding principal balance of the WHMT (as defined in paragraph (g)(1)(iii)(D) of this section) as of the later of January 1st of that year or the trust's start-up date. For purposes of applying the special WHMT de minimis test in this paragraph (c)(2)(iv)(D)(*2*), amounts that result from the complete or partial payment of the outstanding principal balance of the mortgages held by the trust are not included in the amount of trust sales proceeds.

(*3*) *Effect of clean-up call.* If a WHFIT fails to meet either de minimis test described in this paragraph (c)(2)(iv)(D) solely as the result of a clean-up call, as defined in paragraph (b)(6) of this section, the WHFIT will be treated as having met the de minimis test.

(E) *Qualified NMWHFIT exception.* The qualified NMWHFIT exception is satisfied if a NMWHFIT has a start-up date that is before February 23, 2006 and the calendar year for which the trustee is reporting begins before January 1, 2011.

(v) *Redemptions and sales of WHFIT interests*—(A) *Redemptions*—(*1*) *In general.* Unless paragraph (c)(2)(v)(C) of this section (regarding certain NMWHFITs with dividend income) applies, for each date on which the amount of redemption proceeds for the redemption of a trust interest is determined, the trustee must provide information to enable a requesting person to determine—

(*i*) The redemption proceeds (as defined in paragraph (b)(15) of this section) per trust interest on that date;

(*ii*) The redemption asset proceeds (as defined in paragraph (b)(14) of this section) per trust interest on that date; and

(*iii*) The gross income that is attributable to the redeeming beneficial owner for the portion of the calendar year that the redeeming beneficial owner held its interest (including income earned by the WHFIT after the date of the last income distribution).

(*2*) *In-kind redemptions.* The value of the assets received with respect to an in-kind redemption (as defined in paragraph (b)(8) of this section) is not required to be reported under this paragraph (c)(2)(v)(A). Information regarding the income attributable to a redeeming beneficial owner must, however, be reported under paragraph (c)(2)(v)(A)(*1*)(*iii*) of this section.

(B) *Sale of a trust interest*—Unless paragraph (c)(2)(v)(C) (regarding certain NMWHFITs with dividend income) of this section applies, if a secondary market for trust interests in the WHFIT is established, the trustee must provide, for each day of the calendar year, information to enable a requesting person to determine—

(*1*) The sale asset proceeds (as defined in paragraph (b)(17) of this section) per trust interest on that date; and

(*2*) The gross income that is attributable to a selling beneficial owner and to a purchasing beneficial owner for the portion of the calendar year that each held the trust interest.

(C) *Exception for certain NMWHFITs with dividend income.* The trustee of a NMWHFIT to which this paragraph applies is not required to report the information described in paragraph (c)(2)(v)(A) (regarding redemptions) or (c)(2)(v)(B) (regarding sales) of this section. However, the trustee must report to requesting persons, for each date on which the amount of redemption proceeds to be paid for the redemption of a trust interest is determined, information that will enable requesting persons to determine the redemption proceeds per trust interest on that date. The trustee also must provide requesting persons with a statement that this paragraph applies to the NMWHFIT. This paragraph applies to a NMWHFIT if substantially all the income of the NMWHFIT consists of dividends (as defined in section 6042(b) and the regulations thereunder) and—

(*1*) The trustee is required by the governing document of the NMWHFIT to make distributions of all cash (less reasonably required reserve funds) held by the NMWHFIT no less frequently than monthly; or

(*2*) The qualified NMWHFIT exception of paragraph (c)(2)(iv)(E) of this section is satisfied.

(vi) *Information regarding bond premium.* The trustee generally must report information that enables a beneficial owner to determine, in any manner that is reasonably consistent with section 171, the amount of the beneficial owner's amortizable bond premium, if any, for each calendar year. However, if for the calendar year, a NMWHFIT meets either the general WHFIT de minimis test of paragraph (c)(2)(iv)(D)(*1*) of this section or the qualified NMWHFIT exception of paragraph (c)(2)(iv)(E) of this section, the trustee of such NMWHFIT is not required to report information regarding bond premium.

(vii) *Information regarding market discount.* The trustee generally must report information that enables a beneficial owner to determine, in any manner reasonably consistent with section 1276 (including section 1276(a)(3)), the amount of the market discount that has accrued during the calendar year. However, if for the calendar year, a NMWHFIT meets either the general WHFIT de minimis test of paragraph (c)(2)(iv)(D)(*1*) of this section or the qualified NMWHFIT exception of paragraph (c)(2)(iv)(E) of this section, the trustee of such NMWHFIT is not required to provide information regarding market discount.

(viii) *Other information.* The trustee must provide any other information necessary for a beneficial owner of a trust interest to report, with reasonable accuracy, the items (as defined in paragraph (b)(9) of this section) attributable to the portion of the trust treated as owned by the beneficial owner under section 671.

(3) *Identifying the representative who will provide trust information.* The trustee must identify a representative of the WHFIT who will provide the information specified in this paragraph (c). The trustee also may identify an Internet website at which the trustee will provide the information specified in this paragraph (c). This information must be—

(i) Printed in a publication generally read by, and available to, requesting persons;

(ii) Stated in the trust's prospectus; or

(iii) Posted at the trustee's Internet website.

(4) *Time and manner of providing information*—(i) *Time*—(A) *In general.* Except as provided in paragraph (c)(4)(i)(B) of this section, a trustee must provide the information specified in this paragraph (c) to requesting persons on or before the later of—

(*1*) The 30th day after the close of the calendar year to which the request relates; or

(*2*) The day that is 14 days after the receipt of the request.

(B) *Trusts holding interests in other WHFITs or in REMICs.* If the WHFIT holds an interest in one or more other WHFITs or holds one or more REMIC regular interests, or holds both, a trustee must provide the information specified in this paragraph (c) to requesting persons on or before the later of—

(*1*) The 44th day after the close of the calendar year to which the request relates; or

(*2*) The day that is 28 days after the receipt of the request.

(ii) *Manner.* The information specified in this paragraph (c) must be provided—

(A) By written statement sent by first class mail to the address provided by the requesting person;

(B) By causing it to be printed in a publication generally read by and available to requesting persons and by notifying requesting persons in writing of the publication in which it will appear, the date on which it will appear, and, if possible, the page on which it will appear;

(C) By causing it to be posted at an Internet website, provided the trustee identifies the website under paragraph (c)(3) of this section;

(D) By electronic mail provided that the requesting person requests that the trustee furnish the information by electronic mail and the person furnishes an electronic address; or

(E) By any other method agreed to by the trustee and the requesting person.

(iii) *Inclusion of information with respect to all calculation periods.* If a trustee calculates WHFIT information using a calculation period other than a calendar year, the trustee must provide information for each calculation period that falls within the calendar year requested.

(5) *Requesting information from a WHFIT*—(i) *In general.* Requesting persons may request the information specified in this paragraph (c) from a WHFIT.

(ii) *Manner of requesting information.* In requesting WHFIT information, a requesting person must specify the WHFIT and the calendar year for which information is requested.

(iii) *Period of time during which a requesting person may request WHFIT information.* For the life of the WHFIT and for five years following the date of the WHFIT's termination, a requesting person may request the information specified in this paragraph (c) for any calendar year of the WHFIT's existence beginning with the 2007 calendar year.

(6) *Trustee's requirement to retain records.* For the life of the WHFIT and for five years following the date of termination of the WHFIT, the trustee must maintain in its records a copy of the information required to be provided to requesting persons this paragraph (c) for each calendar year beginning with the 2007 calendar year. For a period of five years following the close of the calendar year to which the data pertains, the trustee also must maintain in its records such supplemental data as may be necessary to establish that the information provided to requesting persons is correct and meets the requirements of this paragraph (c).

(d) *Form 1099 requirement for trustees and middlemen*—(1) *Obligation to file Form 1099 with the IRS*—(i) *In general.* Except as provided in paragraphs (d)(1)(ii) and (iii) of this section—

(A) The trustee must file with the IRS the appropriate Forms 1099, reporting the information specified in paragraph (d)(2) of this section with respect to any TIH who holds an interest in the WHFIT directly and not through a middleman; and

(B) Every middleman must file with the IRS the appropriate Forms 1099, reporting the information specified in paragraph (d)(2) of this section with respect to any TIH on whose behalf or account the middleman holds an interest in the WHFIT or acts as an intermediary.

(ii) *Forms 1099 not required for exempt recipients*—(A) *In general.* A Form 1099 is not required with respect to a TIH who is an exempt recipient (as defined in paragraph (b)(7) of this section), unless the trustee or middleman backup withholds under section 3406 on payments made to an exempt recipient (because, for example, the exempt recipient has failed to furnish a Form W–9 on request). If the trustee or middleman backup withholds, then the trustee or middleman is required to file a Form 1099 under this paragraph (d) unless the trustee or middleman refunds the amount withheld in accordance with § 31.6413(a)–3 of this chapter.

(B) *Exempt recipients must include WHFIT information in computing taxable income.* A beneficial owner who is an exempt recipient must obtain WHFIT information and must include the items (as defined in paragraph (b)(9) of this section) of the WHFIT in computing its taxable income on its federal income tax return. Paragraphs (c)(3) and (h) of this section provide rules for exempt recipients to obtain information from a WHFIT.

(iii) *Reporting and withholding with respect to foreign persons.* The items of the WHFIT attributable to a TIH who is not a United States person must be reported, and amounts must be withheld, as provided under subtitle A, chapter 3 of the Internal Revenue Code (sections 1441 through 1464) and the regulations thereunder and not reported under this paragraph (d).

(2) *Information to be reported*—(i) *Determining amounts to be provided on Forms 1099.* The amounts reported to the IRS for a calendar year by a trustee or middleman on the appropriate Form 1099 must be consistent with the information provided by the trustee under paragraph (c) of this section and must reflect with reasonable accuracy the amount of each item required to be reported on a Form 1099 that is attributable (or if permitted under paragraphs (d)(2)(ii)(D) and (E) of this section, distributed) to the TIH. If the trustee, in providing WHFIT information, uses the safe harbors in paragraph (f)(1) or (g)(1) of this section, then the trustee or middleman must calculate the information to be provided to the IRS on the Forms 1099 in accordance with paragraph (f)(2) or (g)(2) of this section, as appropriate.

(ii) *Information to be provided on Forms 1099.* The trustee or middleman must include on the appropriate Forms 1099:

(A) *Taxpayer information.* The name, address, and taxpayer identification number of the TIH;

(B) *Information regarding the person filing the Form 1099.* The name, address, taxpayer identification number, and telephone number of the person required to file the Form 1099;

(C) *Gross income.* All items of gross income of the WHFIT attributable to the TIH for the calendar year (including OID and all amounts of income attributable to a selling, purchasing, or redeeming TIH for the portion of the calendar year that the TIH held its interest (unless paragraph (c)(2)(v)(C) of this section (regarding certain NMWHFITs with dividend income) applies));

(D) *Non pro-rata partial principal payments.* All non pro-rata partial principal payments (as defined in paragraph (b)(13) of this section) received by the WHFIT that are attributable (or distributed, in the case of a trustee or middleman reporting under paragraph (f)(2)(iii) of this section) to the TIH;

(E) *Trust sales proceeds.* All trust sales proceeds (as defined in paragraph (b)(21) of this section) that are attributable to the TIH for the calendar year, if any, or, if paragraph (c)(2)(iv)(B) of this section (regarding certain NMWHFITs) applies, the amount of trust sales proceeds distributed to the TIH for the calendar year;

(F) *Reporting redemptions.* All redemption asset proceeds (as defined in paragraph (b)(14) of this section) paid to the TIH for the calendar year, if any, or, if paragraph (c)(2)(v)(C) of this section (regarding certain NMWHFITs with dividend income) applies, all redemption proceeds (as defined in paragraph (b)(15) of this section) paid to the TIH for the calendar year;

(G) *Reporting sales of a trust interest on a secondary market.* All sales asset proceeds (as defined in paragraph (b)(17) of this section) paid to a TIH for the sale of a trust interest or interests on a secondary market established for the WHFIT for the calendar year, if any, or, if paragraph (c)(2)(v)(C) of this section (regarding certain NMWHFITs with dividend income) applies, all sales proceeds (as defined in paragraph (b)(18) of this section) paid to the TIH for the calendar year; and

(H) *Other information.* Any other information required by the Form 1099.

(3) *Time and manner of filing Forms 1099*—(i) *Time and place.* The Forms 1099 required to be filed under this paragraph (d) must be filed on or before February 28 (March 31, if filed electronically) of the year following the year for which the Forms 1099 are being filed. The returns must be filed with the appropriate Internal Revenue Service Center, at the address listed in the instructions for the Forms 1099. For extensions of time for filing returns under this section, see § 1.6081–1, the instructions for the Forms 1099, and applicable revenue procedures (see § 601.601(d)(2) of this chapter). For magnetic media filing requirements, see § 301.6011–2 of this chapter.

(ii) *Reporting trust sales proceeds, redemption asset proceeds, redemption proceeds, sale asset proceeds, sales proceeds and non pro-rata partial principal payments*—(A) *Form to be used.* Trust sales proceeds, redemption asset proceeds, redemption proceeds, sale asset proceeds, sales proceeds, and non pro-rata partial principal payments are to be reported on the same type of Form 1099 as that required for reporting gross proceeds under section 6045.

(B) *Appropriate reporting for in-kind redemptions.* The value of the assets distributed with respect to an in-kind redemption is not required to be reported to the IRS. Unless paragraph (c)(2)(v)(C) of this section applies, the trustee or middleman must report the gross income attributable to the redeemed trust interest for the calendar year up to the date of the redemption under paragraph (d)(2)(ii)(C) of this section.

(e) *Requirement to furnish a written tax information statement to the TIH*—(1) *In general.* Every trustee or middleman required to file appropriate Forms 1099 under paragraph (d) of this section with respect to a TIH must furnish to that TIH (the person whose identifying number is required to be shown on the form) a written tax information statement showing the information described in paragraph (e)(2) of this section. The amount of a trust item reported to a TIH under this paragraph (e) must be consistent with the information reported to the IRS with respect to the TIH under paragraph (d) of this section. Information provided in this written statement must be determined in accordance with the rules provided in paragraph (d)(2)(i) of this section (regardless of whether the information was required to be provided on a Form 1099). Further, the trustee or middleman must separately state on the written tax information statement any items that, if taken into account separately by that TIH, would result in an income tax liability that is different from the income tax liability that would result if the items were not taken into account separately.

(2) *Information required.* For the calendar year, the written tax information statement must meet the following requirements:

(i) *WHFIT information.* The written tax information statement must include the name of the WHFIT and the identifying number of the WHFIT ;

(ii) *Identification of the person furnishing the statement.* The written tax information statement must include the name, address, and taxpayer identification number of the person required to furnish the statement;

(iii) *Items of income, expense, and credit.* The written tax information statement must include information regarding the items of income (that is, the information required to be reported to the IRS on Forms 1099), expense (including affected expenses), and credit that are attributable to the TIH for the calendar year;

(iv) *Non pro-rata partial principal payments.* The written tax information statement must include the information required to be reported to the IRS on Forms 1099 under paragraph (d)(2)(ii)(D) of this section (regarding the non pro-rata partial principal payments that are attributable (or distributed, in the case of a trustee or middleman reporting under paragraph (f)(2)(iii) of this section) to the TIH for the calendar year).

(v) *Asset sales and dispositions*—(A) *General rule.* Unless paragraph (c)(2)(iv)(B) (regarding the exception for certain NMWHFITs) or (c)(2)(iv)(C) (regarding the exception for certain WHMTs) of this section applies, the written tax information statement must include, with respect to each sale or disposition of a WHFIT asset for the calendar year—

(*1*) The date of sale or disposition;

(*2*) Information regarding the trust sales proceeds that are attributable to the TIH as a result of the sale or disposition; and

(*3*) Information that will enable the TIH to allocate with reasonable accuracy a portion of the TIH's basis in the TIH's trust interest to the sale or disposition.

(B) *Special rule for certain NMWHFITs and WHMTs.* In the case of a NMWHFIT to which paragraph (c)(2)(iv)(B) of this section applies or in the case of a WHMT to which paragraph (c)(2)(iv)(C) of this section applies, the written tax information statement must include, with respect to asset sales and dispositions, only the information required to be reported to the IRS on Form 1099 under paragraph (d)(2)((ii)(E) of this section.

(vi) *Redemption or sale of a trust interest.* The written tax information statement must include the information required to be reported to the IRS on Forms 1099 under paragraphs (d)(2)(ii)(F) and (G) of this section (regarding the sales and redemptions of trust interests made by the TIH for the calendar year);

(vii) *Information regarding market discount and bond premium.* The written tax information statement must include the information required to be reported by the trustee under paragraphs (c)(2)(vi) and (vii) of this section (regarding bond premium and market discount);

(viii) *Other information.* The written tax information statement must include any other information necessary for the TIH to report, with reasonable accuracy for the calendar year, the items (as defined in paragraph (b)(9) of this section) attributable to the portion of the trust treated as owned by the TIH under section 671. The written tax information statement may include information with respect to a trust item on a per trust interest basis if the trustee has reported (or calculated) the information with respect to that item on a per trust interest basis and information with respect to that item is not required to be reported on a Form 1099; and

(ix) *Required statement.* The written tax information statement must inform the TIH that the items of income, deduction, and credit, and any other information shown on the statement must be taken into account in computing the taxable income and credits of the TIH on the Federal income tax return of the TIH. If the written tax information statement reports that an amount of qualified dividend income is attributable to the TIH, the written tax information statement also must inform the TIH that the TIH must meet the requirements of section 1(h)(11)(B)(iii) to treat the dividends as qualified dividends.

(3) *Due date and other requirements.* The written tax information statement

must be furnished to the TIH on or before March 15 of the year following the calendar year for which the statement is being furnished.

(4) *Requirement to retain records.* For a period of no less than five years from the due date for furnishing the written tax information statement, a trustee or middleman must maintain in its records a copy of any written tax information statement furnished to a TIH, and such supplemental data as may be required to establish the correctness of the statement.

(f) *Safe harbor for providing information for certain NMWHFITs*—(1) *Safe harbor for trustee reporting of NMWHFIT information*—The trustee of a NMWHFIT that meets the requirements of paragraph (f)(1)(i) of this section is deemed to satisfy paragraph (c)(1)(i) of this section, if the trustee calculates and provides WHFIT information in the manner described in this paragraph (f) and provides a statement to a requesting person giving notice that information has been calculated in accordance with this paragraph (f)(1).

(i) *In general.* (A) *Eligibility to report under this safe harbor.* Only NMWHFITs that meet the requirements set forth in paragraphs (f)(1)(i)(A)(*1*) and (*2*) of this section may report under this safe harbor.

(*1*) Substantially all of the NMWHFIT's income is from dividends (as defined in section 6042(b) and the regulations thereunder) or interest (as defined in section 6049(b) and the regulations thereunder); and

(*2*) All trust interests have identical value and rights

(B) *Consistency requirements.* The trustee must—

(*1*) Calculate all trust items subject to the safe harbor consistent with the safe harbor; and, (*2*) Report under this paragraph (f)(1) for the life of the NMWHFIT; or, if the NMWHFIT has a start-up date before January 1, 2007, the NMWHFIT must begin reporting under this paragraph (f)(1) as of January 1, 2007 and must continue to report under this paragraph for the life of the NMWHFIT.

(ii) *Reporting NMWHFIT income and expenses.* A trustee must first determine the total amount of NMWHFIT distributions (both actual and deemed) for the calendar year and then express each income or expense item as a fraction of the total amount of NMWHFIT distributions. These fractions (hereinafter referred to as factors) must be accurate to at least four decimal places.

(A) *Step One: Determine the total amount of NMWHFIT distributions for the calendar year.* The trustee must determine the total amount of NMWHFIT distributions (actual and deemed) for the calendar year. If the calculation of the total amount of NMWHFIT distributions under this paragraph (f)(1)(ii)(A) results in a zero or a negative number, the trustee may not determine income and expense information under this paragraph (f)(1)(ii)(A) (but may report all other applicable items under this paragraph (f)(1)). The total amount of NMWHFIT distributions equals the amount of NMWHFIT funds paid out to all TIHs (including all trust sales proceeds, all principal receipts, and all redemption proceeds) for the calendar year—

(*1*) Increased by—

(*i*) All amounts that would have been distributed during the calendar year, but were instead reinvested pursuant to a reinvestment plan; and

(*ii*) All cash held for distribution to TIHs as of December 31 of the year for which the trustee is reporting; and

(*2*) Decreased by—

(*i*) All cash distributed during the current year that was included in a year-end cash allocation factor (see paragraph (f)(1)(ii)(C)(*1*) of this section) for a prior year;

(*ii*) All redemption asset proceeds paid for the calendar year, or if paragraph (c)(2)(v)(C) of this section applies to the NMWHFIT, all redemption proceeds paid for the calendar year;

(*iii*) All trust sales proceeds distributed during the calendar year; and

(*iv*) All non pro-rata partial principal payments distributed during the calendar year.

(*3*) For the purpose of determining the amount of all redemption asset proceeds or redemption proceeds paid for the calendar year with respect to paragraph (f)(1)(ii)(A)(*2*)(*ii*) of this section, the value of the assets (not including cash) distributed with respect to an in-kind redemption is disregarded. Any cash distributed as part of the redemption must be included in the total amount of NMWHFIT distributions.

(B) *Step Two: Determine factors that express the ratios of NMWHFIT income and expenses to the total amount of NMWHFIT distributions.* The trustee must determine factors that express the ratios of NMWHFIT income and expenses to the total amount of NMWHFIT distributions as follows:

(*1*) *Income factors.* For each item of income generated by the NMWHFIT's assets for the calendar year, the trustee must determine the ratio of the gross amount of that item of income to the total amount of NMWHFIT distributions for the calendar year; and

(*2*) *Expense factors.* For each item of expense paid by a NMWHFIT during the calendar year, the trustee must determine the ratio of the gross amount of that item of expense to the total amount of NMWHFIT distributions for the calendar year.

(C) *Step Three: Determine adjustments for reconciling the total amount of NMWHFIT distributions (determined under Step One) with amounts actually paid to TIHs.* Paragraph (f)(1)(ii)(B) of this section (Step Two) requires an item of income or expense to be expressed as a ratio of that item to the total amount of NMWHFIT distributions as determined in paragraph (f)(1)(ii)(A) of this section (Step One). A TIH's share of the total amount of NMWHFIT distributions may differ from the amount actually paid to that TIH. A trustee, therefore, must provide information that can be used to compute a TIH's share of the total amount of NMWHFIT distributions based on the amount actually paid to the TIH. A trustee satisfies this requirement by providing a current year-end cash allocation factor, a prior year cash allocation factor, and the date on which the prior year cash was distributed to TIHs (prior year cash distribution date).

(*1*) *The current year-end cash allocation factor.* The current year-end cash allocation factor is the amount of cash held for distribution to TIHs by the NMWHFIT as of December 31 of the calendar year for which the trustee is reporting, divided by the number of trust interests outstanding as of that date.

(*2*) *The prior year cash allocation factor.* The prior year cash allocation factor is the amount of the distribution during the calendar year for which the trustee is reporting that was included in determining a year-end cash allocation factor for a prior year, divided by the number of trust interests outstanding on the date of the distribution.

(iii) *Reporting non pro-rata partial principal payments under the safe harbor.* The trustee must provide a list of dates on which non pro-rata partial principal payments were distributed by the trust, and the amount distributed, per trust interest.

(iv) *Reporting sales and dispositions of NMWHFIT assets under the safe harbor*—(A) *NMWHFITs that must report under the general rule*—(*1*) *In general.* If a NMWHFIT must report under the general rule of paragraph (c)(2)(iv)(A) of this section, the trustee must provide a list of dates (from earliest to latest) on which sales or

dispositions of NMWHFIT assets occurred during the calendar year for which the trustee is reporting and, for each date identified, provide—

(*i*) The trust sales proceeds received by the trust, per trust interest, with respect to the sales and dispositions, on that date;

(*ii*) The trust sales proceeds distributed to TIHs, per trust interest, with respect to the sales and dispositions on that date, and the date that the trust sales proceeds were distributed to the TIHs; and

(*iii*) The ratio (expressed as a percentage) of the assets sold or disposed of on that date to all assets held by the NMWHFIT.

(*2*) *Determination of the portion of all assets held by the NMWHFIT that the assets sold or disposed of represented*—

(*i*) If a NMWHFIT terminates within twenty-four months of its start-up date, the ratio of the assets sold or disposed of on that date to all assets held by the NMWHFIT is based on the fair market value of the NMWHFIT's assets as of the start-up date; or

(*ii*) If a NMWHFIT terminates more than twenty-four months after its start-up date, the ratio of the assets sold or disposed of on that date to all assets held by the NMWHFIT is based on the fair market value of the NMWHFIT's assets as of the date of the sale or disposition.

(B) *NMWHFITs excepted from the general rule*. If paragraph (c)(2)(iv)(B) of this section applies to the NMWHFIT, the trustee must provide a list of dates on which trust sales proceeds were distributed, and the amount of trust sales proceeds, per trust interest, that were distributed on that date. The trustee also must also provide requesting persons with the statement required by paragraph (c)(2)(iv)(B) of this section.

(v) *Reporting redemptions under the safe harbor*—(A) *In general*. The trustee must:

(*1*) Provide a list of dates on which the amount of redemption proceeds paid for the redemption of a trust interest was determined and the amount of the redemption asset proceeds determined per trust interest on that date, or if paragraph (c)(2)(v)(C) of this section applies to the NMWHFIT, the amount of redemption proceeds determined on that date; or

(*2*) Provide to each requesting person that held (either for its own behalf or for the behalf of a TIH) a trust interest that was redeemed during the calendar year, the date of the redemption and the amount of the redemption asset proceeds per trust interest determined on that date, or if paragraph (c)(2)(v)(C) of this section applies to the NMWHFIT, the amount of the redemption proceeds determined for that date; and

(B) *Paragraph (c)(2)(v)(C) statement*. If paragraph (c)(2)(v)(C) of this section applies to the NMWHFIT, the trustee must provide a statement to requesting persons to the effect that the trustee is providing information consistent with paragraph (c)(2)(v)(C) of this section.

(vi) *Reporting the sale of a trust interest under the safe harbor*. If paragraph (c)(2)(v)(C) of this section does not apply to the NMWHFIT, the trustee must provide, for each day of the calendar year, the amount of cash held for distribution, per trust interest, by the NMWHFIT on that date. If the trustee is able to identify the date on which trust interests were sold on the secondary market, the trustee alternatively may provide information for each day on which sales of trust interests occurred rather than for each day during the calendar year. If paragraph (c)(2)(v)(C) of this section applies to the NMWHFIT, the trustee is not required to provide any information under this paragraph (f)(1)(vi), other than a statement that the NMWHFIT meets the requirements to report under paragraph (c)(2)(v)(C) of this section.

(vii) *Reporting OID information under the safe harbor*. The trustee must provide, for each calculation period, the average aggregate daily accrual of OID per $1,000 of original principal amount.

(viii) *Reporting market discount information under the safe harbor*—(A) *In general*. If the trustee of a NMWHFIT is required to provide information regarding market discount under paragraph (c)(2)(vii) of this section, the trustee must provide the information required under paragraph (f)(1)(iv)(A)(*1*)(*iii*) of this section. If the trustee is not required to provide market discount information under paragraph (c)(2)(vii) of this section (because the NMWHFIT meets either the *de minimis* test of paragraph (c)(2)(iv)(D) of this section, or the qualified NMWHFIT exception of paragraph (c)(2)(iv)(E) of this section), the trustee is not required under this paragraph (f) to provide any information regarding market discount.

(B) *Reporting market discount information under the safe harbor when the yield of the debt obligations held by the WHFIT is expected to be affected by prepayments*. [Reserved.]

(ix) *Reporting bond premium information under the safe harbor*. [Reserved.]

(x) *Reporting additional information*. If a requesting person cannot use the information provided by the trustee under paragraphs (f)(1)(ii) through (ix) of this section to determine with reasonable accuracy the trust items that are attributable to a TIH, the requesting person must request, and the trustee must provide, additional information to enable the requesting person to determine the trust items that are attributable to the TIH. See, for example, paragraph (f)(2)(ii)(A)(*4*) of this section which requires a middleman to request additional information from the trustee when the total amount of WHFIT distributions attributable to a TIH equals zero or less.

(2) *Use of information provided by trustees under the safe harbor for NMWHFITs*—(i) *In general*. If a trustee reports NMWHFIT items in accordance with paragraph (f)(1) of this section, the information provided with respect to those items on the Forms 1099 required under paragraph (d) of this section to be filed with the IRS and on the statement required under paragraph (e) of this section to be furnished to the TIH must be determined as provided in this paragraph (f)(2).

(ii) *Determining NMWHFIT income and expense under the safe harbor*. The trustee or middleman must determine the amount of each item of income and expense attributable to a TIH as follows—

(A) *Step One: Determine the total amount of NMWHFIT distributions attributable to the TIH*. To determine the total amount of NMWHFIT distributions attributable to a TIH for the calendar year, the total amount paid to, or credited to the account of, the TIH during the calendar year (including amounts paid as trust sales proceeds or partial non-pro rata principal payments, redemption proceeds, and sales proceeds) is—

(*1*) Increased by—

(*i*) All amounts that would have been distributed during the calendar year to the TIH, but that were reinvested pursuant to a reinvestment plan (unless another person (for example, the custodian of the reinvestment plan) is responsible for reporting these amounts under paragraph (d) of this section); and

(*ii*) An amount equal to the current year-end cash allocation factor (provided by the trustee in accordance with paragraph (f)(1)(ii)(C)(*1*) of this section) multiplied by the number of trust interests held by the TIH as of December 31 of the calendar year for which the trustee is reporting; and

(*2*) Decreased by—

(*i*) An amount equal to the prior year cash allocation factor (provided by the trustee in accordance with paragraph (f)(1)(ii)(C)(*2*) of this section) multiplied by the number of trust interests held by the TIH on the date of the distribution;

(*ii*) An amount equal to all redemption asset proceeds paid to the TIH for the calendar year, or if paragraph (c)(2)(v)(C) of this section applies to the NMWHFIT, an amount equal to all redemption proceeds paid to the TIH for the calendar year;

(*iii*) An amount equal to all sale asset proceeds paid to the TIH for the calendar year, or if paragraph (c)(2)(v)(C) of this section applies to the NMWHFIT, the amount of sales proceeds paid to the TIH for the calendar year;

(*iv*) In the case of a TIH that purchased a trust interest in a NMWHFIT to which paragraph (c)(2)(v)(C) of this section does not apply, an amount equal to the cash held for distribution per trust interest on the date that the TIH acquired its interest, multiplied by the trust interests acquired on that date;

(*v*) The amount of the trust sales proceeds distributed to the TIH, calculated as provided in paragraph (f)(2)(iv)(A)(*3*) of this section; and

(*vi*) The amount of non pro-rata partial principal prepayments distributed to the TIH during the calendar year, calculated as provided in paragraph (f)(2)(iii) of this section.

(*3*) *Treatment of in-kind distributions under this paragraph (f)(2)(i).* The value of the assets (not including cash) received with respect to an in-kind redemption is not included in the amount used in paragraph (f)(2)(ii)(A)(*2*)(*ii*) of this section. The cash distributed as part of the redemption, however, must be included in the total amount of NMWHFIT distributions paid to the TIH.

(*4*) *The total amount of distributions attributable to a TIH calculated under this paragraph (f)(2)(i)(A) equals zero or less.* If the total amount of distributions attributable to a TIH, calculated under this paragraph (f)(2)(i)(A), equals zero or less, the trustee or middleman may not report the income and expense attributable to the TIH under this paragraph (f)(2)(i). The trustee or middleman must request additional information from the trustee of the NMWHFIT to enable the trustee or middleman to determine with reasonable accuracy the items of income and expense that are attributable to the TIH. The trustee or middleman must report the other items subject to paragraph (f)(1) of this section in accordance with this paragraph (f)(2).

(B) *Step Two: Apply the factors provided by the trustee to determine the items of income and expense that are attributable to the TIH.* The amount of each item of income (other than OID) and each item of expense attributable to a TIH is determined as follows—

(*1*) *Application of income factors.* For each income factor, the trustee or middleman must multiply the income factor by the total amount of NMWHFIT distributions attributable to the TIH for the calendar year (as determined in paragraph (f)(2)(i)(A) of this section).

(*2*) *Application of expense factors.* For each expense factor, the trustee or middleman must multiply the expense factor by the total amount of NMWHFIT distributions attributable to the TIH for the calendar year (as determined in paragraph (f)(2)(i)(A) of this section).

(iii) *Reporting non pro-rata partial principal payments under the safe harbor.* To determine the amount of non pro-rata partial principal payments that are distributed to a TIH for the calendar year, the trustee or middleman must aggregate the amount of non pro-rata partial principal payments distributed to a TIH for each day that non pro-rata principal payments were distributed. To determine the amount of non pro-rata principal payments that are distributed to a TIH on each distribution date, the trustee or middleman must multiply the amount of non-pro rata principal payments per trust interest distributed on that date by the number of trust interests held by the TIH.

(iv) *Reporting sales and dispositions of NMWHFIT assets under the safe harbor—(A) Reporting under the safe harbor if the general rules apply to the NMWHFIT.* Unless paragraph (c)(2)(iv)(B) of this section applies, the trustee or middleman must comply with paragraphs (f)(2)(iv)(A)(*1*), (*2*), and (*3*) of this section.

(*1*) *Form 1099.* The trustee or middleman must report the amount of trust sales proceeds attributable to the TIH for the calendar year on Form 1099. To determine the amount of trust sales proceeds attributable to a TIH for the calendar year, the trustee or middleman must aggregate the total amount of trust sales proceeds attributable to the TIH for each date on which the NMWHFIT sold or disposed of an asset or assets. To determine the total amount of trust sales proceeds attributable to a TIH for each date that the NMWHFIT sold or disposed of an asset or assets, the trustee or middleman multiplies the amount of trust sales proceeds received by the NMWHFIT per trust interest on that date by the number of trust interests held by the TIH on that date.

(*2*) *The written tax information statement furnished to the TIH.* The written tax information statement required to be furnished to the TIH under paragraph (e) of this section must include a list of dates (in order, from earliest to latest) on which sales or dispositions of trust assets occurred during the calendar year and provide, for each date identified—

(i) The trust sales proceeds received by the trust, per trust interest, with respect to the sales or dispositions of trust assets on that date; and

(*ii*) The information provided by the trustee under paragraph (f)(1)(iv)(B)(*2*) of this section regarding the ratio of the assets sold or disposed of on that date to all the assets of the NMWHFIT held on that date, prior to such sale or disposition.

(3) *Calculating the total amount of trust sales proceeds distributed to the TIH.* To determine the total amount of NMWHFIT distributions attributable to a TIH, the trustee or middleman must calculate the amount of trust sales proceeds distributed to the TIH for the calendar year. (See paragraph (f)(2)(ii)(A)(*2*)(*v*) of this section.) To determine the amount of trust sales proceeds distributed to a TIH for the calendar year, the trustee or middleman must aggregate the total amount of trust sales proceeds distributed to the TIH for each date on which the NMWHFIT distributed trust sales proceeds. To determine the total amount of trust sales proceeds distributed to a TIH for each date that the NMWHFIT distributed trust sales proceeds, the trustee or middleman must multiply the amount of trust sales proceeds distributed by the NMWHFIT per trust interest on that date by the number of trust interests held by the TIH on that date.

(B) *Reporting under the safe harbor if paragraph (c)(2)(iv)(B) of this section applies to the NMWHFIT.* If paragraph (c)(2)(iv)(B) of this section applies, the trustee or middleman must calculate, in the manner provided in paragraph (f)(2)(iv)(A)(*3*) of this section, the amount of trust sales proceeds distributed to the TIH for the calendar year. The trustee or middleman must report this amount on the Form 1099 filed for the TIH and on the written tax information statement furnished to the TIH.

(v) *Reporting redemptions under the safe harbor*—(A) Except as provided in paragraph (f)(2)(v)(B) or (C) of this section, if the trustee has provided a list of dates for which the amount of the redemption proceeds to be paid for the redemption of a trust interest was determined and the redemption asset proceeds paid for that date, the trustee or middleman must multiply the redemption asset proceeds determined per trust interest for that date by the number of trust interests redeemed by the TIH on that date.

(B) If paragraph (c)(2)(v)(C) of this section applies, and the trustee has provided a list of dates for which the amount of the redemption proceeds to be paid for the redemption of a trust interest was determined and the redemption proceeds determined per trust interest on each date, the trustee or middleman must multiply the redemption proceeds per trust interest for each date by the number of trust interests redeemed by the TIH on that date.

(C) If the trustee has provided the requesting person with information regarding the redemption asset proceeds paid for each redemption of a trust interest held by the middleman for the calendar year, or if paragraph (c)(2)(v)(C) of this section applies and the trustee has provided the amount of redemption proceeds paid for each redemption of a trust interest held by the middleman during the calendar year, the requesting person may use this information to determine the amount of the redemption asset proceeds or redemption proceeds paid to the TIH for the calendar year.

(vi) *Reporting sales of trust interests under the safe harbor*—(A) Except as provided in paragraph (f)(2)(vi)(B) of this section, the trustee or middleman must subtract the amount of cash held for distribution per trust interest on the date of the sale from the sales proceeds paid to the TIH to determine the sale asset proceeds that are to be reported to the TIH for each sale of a trust interest.

(B) If paragraph (c)(2)(v)(C) of this section applies, the trustee or middleman must report the sales proceeds paid to the TIH as a result of each sale of a trust interest.

(vii) *Reporting OID information under the safe harbor*—The trustee or middleman must aggregate the amounts of OID that are allocable to each trust interest held by a TIH for each calculation period. The amount of OID that is allocable to a trust interest, with respect to each calculation period, is determined by multiplying—

(A) The product of the OID factor and the original principal balance of the trust interest, divided by 1,000; by

(B) The number of days during the OID calculation period in that calendar year that the TIH held the trust interest.

(viii) *Reporting market discount information under the safe harbor*—(A) Except as provided in paragraph (f)(2)(viii)(B) of this section, the trustee or middleman must provide the TIH with the information provided under paragraph (f)(1)(vii)(B) of this section.

(B) If paragraph (c)(2)(iv)(B) of this section applies, the trustee and middleman are not required under this paragraph (f)(2) to provide any information regarding market discount.

(ix) *Reporting bond premium information under the safe harbor.* [Reserved]

(3) *Example of the use of the safe harbor for NMWHFITs.* The following example illustrates the use of the factors in this paragraph (f) to calculate and provide NMWHFIT information:

Example: (i) *Facts*—(A) *In general*—(*1*) Trust is a NMWHFIT that holds common stock in ten different corporations and has 100 trust interests outstanding. The start-up date for Trust is December 15, 2006, and the termination date for Trust is March 15, 2008. The agreement governing Trust requires Trust to distribute the cash held by Trust reduced by accrued but unpaid expenses on April 15, July 15, and October 15 of the 2007 calendar year. The agreement also provides that the trust interests will be redeemed by the Trust for an amount equal to the value of the trust interest, as of the close of business, on the day that the trust interest is tendered for redemption. There is no reinvestment plan. A secondary market for interests in Trust will be created by Trust's sponsor and Trust's sponsor will provide Trustee with a list of dates on which sales occurred on this secondary market.

(*2*) As of December 31, 2006, Trust holds $12x for distribution to TIHs on the next distribution date and has no accrued but unpaid expenses. Trustee includes the $12x in determining the year-end cash allocation factor for December 31, 2006.

(B) *Events occurring during the 2007 calendar year*—(*1*) As of January 1, 2007, Broker1 holds ten trust interests in Trust in street name for each of *J* and *A* and Broker2 holds ten trust interests in Trust in street name for *S. J, A*, and *S*; are individual, cash method taxpayers.

(*2*) As of January 1, 2007, the fair market value of the Trust's assets equals $10,000x.

(*3*) During 2007, Trust receives $588x in dividend income. Trustee determines that $400x of the dividend income received during 2007 meets the definition of a qualified dividend in section 1(h)(11)(B)(i) and the holding period requirement in section 1(h)(11)(B)(iii) with respect to the Trust. During 2007, Trust also receives $12x in interest income from investment of Trust's funds pending distribution to TIHs, and pays $45x in expenses, all of which are affected expenses.

(*4*) On April 15, 2007, Trustee distributes $135x, which includes the $12x included in determining the year-end cash allocation factor for December 31, 2006. As a result of the distribution, Broker1 credits *J*'s account and *A*'s account for $13.50x each. Broker2 credits *S*'s account for $13.50x.

(*5*) On June 1, 2007, Trustee sells shares of stock for $1000x to preserve the soundness of the trust. The stock sold on June 1, 2007, equaled 20% of the aggregate fair market value of the assets held by Trust on the start-up date of Trust.

(*6*) On July 15, 2007, Trustee distributes $1,135x, which includes the $1,000x of trust sales proceeds received by Trust for the sale of assets on June 1, 2007. As a result of the distribution, Broker1 credits *J*'s account and *A*'s account for $113.50x each. Broker 2 credits *S*'s account for $113.50x.

(*7*) On September 30 2007, *J*, through Trust's sponsor, sells a trust interest to *S* for $115.35x. Trustee determines that the cash held for distribution per trust interest on September 30 is $1.35x. As a result of the sale, Broker1 credits *J*'s account for $115.35x.

(*8*) On October 15, 2007, Trustee distributes $123x. As a result of the distribution, Broker1 credits *J*'s account for $11.07x and *A*'s account for $12.30x. Broker2 credits *S*'s account for $13.53x.

(*9*) On December 10, 2007, *J* tenders a trust interest to Trustee for redemption through Broker1. Trustee determines that the amount of the redemption proceeds to be paid for a trust interest that is tendered for redemption on December 10, 2007, is $116x, of which $115x represents the redemption asset proceeds. On December 12, 2007, Trustee sells shares of common stock for $115x to have sufficient cash to pay *J*'s redemption proceeds. The stock sold on December 12, 2007, equaled 2% of the aggregate fair market value of all the assets of Trust as of the start up date. On December 17, 2007, Trustee pays the $116x redemption proceeds (including the $115x trust sales proceeds received by Trust for the sale of the stock on December 12) to Broker1 on *J*'s behalf, and Broker1 in turn pays $116x to J as redemption proceeds.

(*10*) On December 10, 2007, *J*, through Trust's sponsor, also sells a trust interest to *S* for $116x. Trustee determines that the cash held for distribution per trust interest on that date is $1x. As a result of the sale, Broker1 credits *J*'s account for $116x.

(*11*) As of December 31, 2007, Trust holds cash of $173x and has incurred $15x in expenses that Trust has not paid. *J* is the only TIH to redeem a trust interest during the calendar year. The sale of two trust interests in Trust by *J* to *S* are the only sales that occurred on the secondary market established by Trust's sponsor during 2007.

(ii) *Trustee reporting*—(A) *Summary of information provided by Trustee.* Trustee meets the requirements of paragraph (f)(1) of this section if Trustee provides the following information to requesting persons:

(*1*) Income and expense information:

Factor for ordinary dividend income.	0.3481
Factor for qualified dividend income.	0.7407
Factor for interest income	0.0222
Factor for affected expenses	0.0833
Current year-end cash allocation factor.	1.5960
Prior year cash allocation factor	0.1200
Prior year cash distribution date	April 15

(*2*) Information regarding asset sales and distributions:

Date of sale	Trust sales proceeds received	Trust sales proceeds distributed and date distributed	Percent of trust sold
June 1	$10.0000x	$10.0000x (July 15)	20
December 12	1.1616x	0.0000x	2

(*3*) Information regarding redemptions:

Date	Redemption asset proceeds
December 10	$115x

(*4*) Information regarding sales of trust interests

Date	Cash held for distribution per trust interest
September 30	$1.35x
December 10	1.00x

(B) *Trustee determines this information as follows:*

(1) *Step One: Trustee determines the total amount of NMWHFIT distributions for the calendar year.* The total amount of NMWHFIT distributions (actual and deemed) for the calendar year for purposes of determining the safe harbor factors is $540x. This amount consists of the amounts paid on each scheduled distribution date during the calendar year ($1135x, $135x, and $123x), plus the total amount paid to *J* as a result of *J*'s redemption of a trust interest ($116x) ($1,135x + $135x + $123x + $116x = $1,509x)—

(*i*) Increased by all cash held for distribution to TIHs as of December 31, 2007 ($158x), which is the cash held as of December 31, 2007 ($173x) reduced by the accrued but unpaid expenses as of December 31, 2007 ($15x), and

(*ii*) Decreased by all amounts distributed during the calendar year but included in the year-end cash allocation factor from a prior year ($12x); all redemption asset proceeds paid for the calendar year ($115x); and all trust sales proceeds distributed during the calendar year ($1,000x).

(*2*) *Step Two: Trustee determines factors that express the ratio of NMWHFIT income (other than OID) and expenses to the total amount of NMWHFIT distributions.* Trustee determines the factors for each item of income earned by Trust and each item of expense as follows:

(*i*) *Ordinary dividend income factor.* The ordinary dividend income factor is 0.3481, which represents the ratio of the gross amount of ordinary dividends ($188x) to the total amount of NMWHFIT distributions for the calendar year ($540x).

(*ii*) *Qualified dividend income factor.* The qualified dividend income factor is 0.7407 which represents the ratio of the gross amount of qualified dividend income ($400x) to the total amount of NMWHFIT distributions for the calendar year ($540x).

(*iii*) *Interest income factor.* The interest income factor is 0.0222, which represents the ratio of the gross amount of interest income ($12x) to the total amount of NMWHFIT distributions for the calendar year ($540x).

(*iv*) *Expense factor.* The affected expenses factor is 0.0833, which represents the ratio of the gross amount of affected expenses paid by Trust for the calendar year ($45x) to the total amount of NMWHFIT distributions for the calendar year ($540x).

(*3*) *Step Three: Trustee determines adjustments for reconciling the total amount of NMWHFIT distributions with amounts paid to TIHs.* To enable requesting persons to determine the total amount of NMWHFIT distributions that are attributable to a TIH based on amounts actually paid to the TIH, the trustee must provide both a current year-end cash allocation factor and a prior year cash allocation factor.

(*i*) *Current year-end cash allocation factor.* The adjustment factor for cash held by Trust at year end is 1.5960, which represents the cash held for distribution as of December 31, 2007 ($158x) (the amount of cash held by Trust on December 31, 2007 ($173x) reduced by accrued, but unpaid, expenses ($15x)), divided by the number of trust interests outstanding at year-end (99).

(*ii*) *Prior Year Cash Allocation Factor.* The adjustment factor for distributions of year-end cash from the prior year is 0.1200, which represents the amount of the distribution during the current calendar year that was included in a year-end cash allocation factor for a prior year ($12x), divided by the number of trust interests outstanding at the time of the distribution (100). The prior year cash distribution date is April 15, 2007.

(*4*) *Reporting sales and dispositions of trust assets*—(*i*) *Application of the de minimis test and the qualified NMWHFIT exception.* The aggregate fair market value of the assets of Trust as of January 1, 2007, was $10,000x. During the 2007 calendar year, Trust received trust sales proceeds of $1115x. Trust sales proceeds received by Trust for the 2007 calendar year equal 11.15% of Trust's fair market value as of January 1, 2007. Accordingly, neither the de minimis test or the qualified NMWHFIT exception is met for the calendar year.

(*ii*) *Information to be provided.* To satisfy the requirements of paragraph (f)(1) of this section with respect to sales and dispositions of Trust's assets, Trustee provides a list of dates on which trust assets were sold during the calendar year, and provides, for each date: the trust sales proceeds (per trust interest) received on that date; the trust sales proceeds distributed to TIHs (per trust interest) with respect to sales or dispositions on that date; the date those trust sales proceeds were distributed, and the ratio of the assets sold or disposed of on that day to all the assets held by Trust. Because Trust will terminate within 15 months of its start-up date, Trustee must use the fair market value of the assets as of the start-up date to determine the portion of Trust sold or disposed of on any particular date.

(*5*) *Reporting redemptions.* Because Trust is not required to make distributions at least as frequently as monthly, and Trust's start-up date is after February 23, 2006, the exception in paragraph (c)(2)(v)(C) of this section does not apply to Trust. To satisfy the requirements of paragraph (f)(1) of this section, Trustee provides a list of dates for which the redemption proceeds to be paid for the redemption of a trust interest was determined for the 2007 calendar year and the redemption assets proceeds paid for each date. During 2007, Trustee only determined the amount of redemption proceeds to be paid for the redemption of a trust interest once, for December 10, 2007, and the redemption asset proceeds determined for that date was $115x.

(*6*) *Reporting sales of trust interest.* Because Trust is not required to make distributions at least as frequently as monthly, and Trust's start up date is after February 23, 2006, the exception in paragraph (c)(2)(v)(C) of this section does not apply to Trust. Sponsor, in accordance with the trust agreement, provides Trustee with a list of dates on which sales on the secondary market occurred. To satisfy the requirements of paragraph (f)(1) of this section, Trustee provides requesting persons with a list of dates on which sales on the secondary market occurred and the amount of cash held for distribution per trust interest on each date. During 2007, two sales occurred on the secondary market. The first sale occurred on September 30, 2007, and the amount of cash held for distribution, per trust interest, on that date is $1.35x. The second sale occurred on December 10, 2007, and the amount of cash held for distribution, per trust interest, on that date is $1.00x.

(*iii*) *Brokers' use of information provided by Trustee.* (A) Broker1 and Broker2 use the information furnished by Trustee under the safe harbor to determine that the following items are attributable to J, A, and S—

With respect to *J*	
Ordinary Dividend Income	$17.89x
Qualified Dividend Income	38.07x
Interest Income	1.14x
Affected Expenses	4.28x
Trust sales proceeds reported on Form 1099	108.13x

Redemption asset proceeds	
For redemption on December 10	115.00x
Sale asset proceeds	
For sale on September 30	114.00x
For sale on December 10	115.00x
With respect to *A*	
Ordinary Dividend Income	18.82x
Qualified Dividend Income	40.04x
Interest Income	1.20x
Affected Expenses	4.50x
Trust sales proceeds reported on Form 1099	11.62x
With respect to *S*	
Ordinary Dividend Income	19.54x
Qualified Dividend Income	41.58x
Interest Income	1.25x
Affected Expenses	4.68x
Trust sales proceeds reported on Form 1099	113.94x

With respect to *J, A*, and *S* (regarding the sales and dispositions executed by Trust during the calendar year)

Date	Trust sales proceeds received per trust interest	Percent of trust sold
June 15	$10.0000x	20
December 12	1.1616x	2

(*B*) The brokers determine the information provided to *J, A*, and *S* as follows—

(*1*) *Step One: Brokers determine the total amount of NMWHFIT distributions attributable to J, A, and S.* Broker1 determines that the total amount of NMWHFIT distributions attributable to *J* is $51.39x and the total amount of NMWHFIT distributions attributable to *A* is $54.06x. Broker2 determines that the total amount of NMWHFIT distributions attributable to *S* is $56.13x.

(*i*) To calculate these amounts the brokers begin by determining the total amount paid to *J, A*, and *S* for the calendar year—

(*A*) The total amount paid to J for the calendar year equals $485.42x and includes the April 15, 2007, distribution of $13.50x, the July 15, 2007, distribution of $113.50x, the sales proceeds for the September 30, 2007, sale of $115.35x, the October 15, 2007, distribution of $11.07x, and the redemption proceeds of $116x and sales proceeds of $116x for the redemption and sale on December 10, 2007.

(*B*) The total amount paid to *A* for the calendar year equals $139.30x and includes the April 15, 2007, distribution of $13.50x, the July 15, 2007, distribution of $113.50x and the October 15, 2007, distribution of $12.30x.

(*C*) The total amount paid to *S* for the calendar year equals $140.53x and includes the April 15, 2007, distribution of $13.50x, the July 15, 2007, distribution of $113.50x and the October 15, 2007, distribution of $13.53x.

(*ii*) The brokers increase the total amount paid to *J, A*, and *S* by an amount equal to the current year-end cash allocation factor (1.5960) multiplied by the number of trust interests held by *J* (7), *A* (10), and *S* (12) as of December 31, 2007; that is for *J*, $11.17x; for *A*, $15.96x; and for *S*, $19.15x.

(*iii*) The brokers reduce the amount paid to *J, A*, and *S* as follows—

(*A*) An amount equal to the prior year cash allocation factor (0.1200), multiplied by the number of trust interests held by *J* (10), *A* (10), and *S* (10) on the date of the prior year cash distribution; that is for *J, A*, and *S*, $1.20x, each;

(*B*) An amount equal to all redemption asset proceeds paid to a TIH for the calendar year; that is, for *J*, $115x;

(*C*) An amount equal to all sales asset proceeds attributable to the TIH for the calendar year; that is for *J*, $229x (for the September 30, 2007, sale: $115.35x − 1.35x (cash held for distribution per trust interest on that date) − $114x; and for the December 10, 2007, sale: $116x − 1.00 (cash held for distribution per trust interest on that date)=$115x));

(*D*) In the case of a purchasing TIH, an amount equal to the amount of cash held for distribution per trust interest at the time the TIH purchased its trust interest, multiplied by the number of trust interests purchased; that is for *S*, $2.35x ($1.35x with respect to the September 30, 2007, sale and $1x with respect to the December 10, 2007, sale);

(*E*) All amounts of trust sales proceeds distributed to the TIH for the calendar year; that is for *J, A*, and *S*, $100. ($100 each, with respect to the June 15, 2007, sale of assets by Trust, and $0 each, with respect to the December 12, 2007, sale of assets by Trust).

(*2*) *Step two: The brokers apply the factors provided by Trustee to determine the Trust's income and expenses that are attributable to J, A, and S.* The amounts of each item of income (other than OID) and expense that are attributable to *J, A*, and *S* are determined by multiplying the factor for that type of income or expense by the total amount of NMWHFIT distributions attributable to *J, A*, and *S* as follows:

(*i*) *Application of factor for ordinary dividends.* The amount of ordinary dividend income attributable to *J* is $17.89x, to *A* is $18.82x, and to *S* is $19.54x. The brokers determine these amounts by multiplying the total amount of NMWHFIT distributions attributable to *J, A*, and *S* ($51.39x, $54.06x, and $56.13x, respectively) by the factor for ordinary dividends (0.3481).

(*ii*) *Application of factor for qualified dividend income.* The amount of qualified dividend income attributable to *J* is $38.07x, to *A* is $40.04x, and to *S* is $41.58x. The brokers determine these amounts by multiplying the total amount of NMWHFIT distributions attributable to *J, A*, and *S* ($51.39x, $54.06x, and $56.13x, respectively) by the factor for qualified dividends (0.7407).

(*iii*) *Application of factor for interest income.* The amount of interest income attributable to *J* is $1.14x, to *A* is $1.20x, and to *S* is $1.25x. The brokers determine these amounts by multiplying the total amount of NMWHFIT distributions attributable to *J, A*, and *S* ($51.39x, $54.06x, and $56.13x, respectively) by the factor for interest (0.0222).

(*iv*) *Application of factor for affected expenses.* The amount of affected expenses attributable to *J* is $4.28x, to *A* is $4.50x, and to *S* is $4.68x. The brokers determine these amounts by multiplying the total amount of NMWHFIT distributions attributable to *J, A*, and *S* ($51.39x, $54.06x, and $56.13x, respectively) by the factor for affected expenses (0.0833).

(*3*) *Brokers reporting of sales and dispositions of trust assets*—(*i*) *Determining the amount of trust sales proceeds to be reported on Form 1099 for J, A, and S.* The amount of trust sales proceeds to be reported on Form 1099 with respect to *J* is $108.13x, to *A* is $111.62x, and to *S* is $113.94x. To determine these amounts, the brokers aggregate the amount of trust sales proceeds attributable to *J, A*, and *S* for each date on which Trust sold or disposed of assets. The brokers determine the amount of trust sales proceeds to be reported with respect to the June 15, 2007, asset sale by multiplying the number of trust interests held by *J* (10), *A* (10) and *S* (10) on that date by the trust sales proceeds received per trust interest on that date ($10x). The brokers determine the amount of trust sales proceeds to be reported with respect to the December 12, 2007, asset sale by multiplying the number of trust interests held by *J* (7), *A* (10) and *S* (12) on that date by the trust sales proceeds received per trust interest on that date ($1.1616x).

(*ii*) *Information provided on the tax information statements furnished to J, A, and S.* The tax information statements furnished to *J, A*, and *S* must include the dates of each sale or disposition (June 15, 2007, and December 12, 2007); the amount of trust sales proceeds per trust interest received on those dates ($10.00x and $1.1616x, respectively); and, the percentage of Trust sold or disposed of on that date (20% and 2%, respectively).

(*4*) *Reporting redemptions.* Broker1 reports on Form 1099 and on the written tax

information statement furnished to *J* that *J* received $115x in redemption asset proceeds for the calendar year.

(*5*) *Reporting sales of trust interests on the secondary market.* Broker1 reports on *J*'s two sales of trust interests. With respect to the sale on September 30, 2007, the sale asset proceeds equals $114x ($115.35x sale proceeds—$1.35x cash held for distribution on that date) and with respect to the sale on December 10, 2007, the sale asset proceeds equal $115x ($116x sale proceeds—$1x cash held for distribution on that date). Broker1 reports these amounts on Form 1099 and on the tax information statement furnished to J.

(g) *Safe Harbor for certain WHMTs*—(1) *Safe harbor for trustee of certain WHMTs for reporting information*—(i) *In general.* The trustee of a WHMT that meets the requirements of paragraph (g)(1)(ii) of this section is deemed to satisfy paragraph (c)(1)(i) of this section, if the trustee calculates and provides WHFIT information in the manner described in this paragraph (g) and provides a statement to the requesting person giving notice that information has been calculated in accordance with this paragraph (g)(1).

(*ii*) *Requirements.* A WHMT must meet the following requirements—

(A) The WHMT must make monthly distributions of the income and principal payments received by the WHMT to its TIHs;

(B) All trust interests in the WHMT must represent the right to receive an equal pro-rata share of both the income and the principal payments received by the WHMT on the mortgages it holds (for example, a WHMT that holds or issues trust interests that qualify as stripped interests under section 1286 may not report under this safe harbor);

(C) The WHMT must—

(*1*) Report under this paragraph (g)(1)(ii) for the life of the WHMT; or

(*2*) If the WHMT has a start-up date before January 1, 2007, the WHMT must begin reporting under this paragraph (g)(1)(ii) as of January 1, 2007, and must continue to report under this paragraph for the life of the WHMT;

(D) The WHMT must calculate all items subject to the safe harbor consistent with the safe harbor;

(E) The assets of the WHMT must be limited to—

(*1*) Mortgages with uniform characteristics;

(*2*) Reasonably required reserve funds; and

(*3*) Amounts received on mortgages or reserve funds and held for distribution to TIHs; and

(F) The aggregate outstanding principal balance (as defined in paragraph (g)(1)(iii)(D) of this section) as of the WHMT's start-up date must equal the aggregate of the original face amounts of all issued trust interests.

(iii) *Reporting WHMT income, expenses, non pro-rata partial principal payments, and sales and dispositions under the safe harbor.* A trustee must comply with each step provided in this paragraph (g)(1)(iii).

(A) *Step One: Determine monthly pool factors.* The trustee must, for each month of the calendar year and for January of the following calendar year, calculate and provide the ratio (expressed as a decimal carried to at least eight places and called a *pool factor*) of—

(*1*) The amount of the aggregate outstanding principal balance of the WHMT as of the first business day of the month; to

(*2*) The amount of the aggregate outstanding principal balance of the WHMT as of the start-up date.

(B) *Step Two: Determine monthly expense factors.* For each month of the calendar year and for each item of expense paid by the WHMT during that month, the trustee must calculate and provide the ratio (expressed as a decimal carried to at least eight places and called an *expense factor*) of—

(*1*) The gross amount, for the month, of each item of expense; to

(*2*) The amount that represents the aggregate outstanding principal balance of the WHMT as of the start-up date, divided by 1,000.

(C) *Step Three: Determine monthly income factors.* For each month of the calendar year and for each item of gross income earned by the WHMT during that month, the trustee must calculate and provide the ratio (expressed as a decimal carried to at least eight places and called an *income factor*) of—

(*1*) The gross amount, for the month, of each item of income, to

(*2*) The amount that represents the aggregate outstanding principal balance of the WHMT as of the start-up date, divided by 1,000.

(D) *Definition of aggregate outstanding principal balance.* For purposes of this paragraph (g)(1)(iii), the amount of the aggregate outstanding principal balance of a WHMT is the aggregate of—

(*1*) The outstanding principal balance of all mortgages held by the WHMT;

(*2*) The amounts received on mortgages as principal payments and held for distribution by the WHMT; and

(*3*) The amount of the reserve fund (exclusive of undistributed income).

(iv) *Reporting OID information under the safe harbor—(A) Reporting OID prior to the issuance of final regulations under section 1272(a)(6)(C)(iii)*—(*1*) For calendar years prior to the effective date of final regulations under section 1272(a)(6)(C)(iii), the trustee must provide, for each month during the calendar year, the aggregate daily accrual of OID per $1,000 of aggregate outstanding principal balance as of the start-up date (daily portion). For purposes of this paragraph (g)(1)(iv), the daily portion of OID is determined by allocating to each day of the month its ratable portion of the excess (if any) of—

(*i*) The sum of the present value (determined under section 1272(a)(6)(B)) of all remaining payments under the mortgages held by the WHMT at the close of the month, and the payments during the month of amounts included in the stated redemption price of the mortgages, over

(*ii*) The aggregate of each mortgage's adjusted issue price as of the beginning of the month.

(*2*) In calculating the daily portion of OID, the trustee must use the prepayment assumption used in pricing the original issue of trust interests.

(B) *Reporting OID after the issuance of final regulations under section 1272(a)(6)(C)(iii).* [Reserved.]

(v) *Reporting market discount information under the safe harbor— (A) Reporting market discount information prior to the issuance of final regulations under sections 1272(a)(6)(C)(iii) and 1276(b)(3).* For calendar years prior to the effective date of final regulations under sections 1272(a)(6)(C)(iii) and 1276(b)(3), the trustee must provide—

(*1*) In the case of a WHMT holding mortgages issued with OID, the ratio (expressed as a decimal carried to at least eight places) of—

(*i*) The OID accrued during the month (calculated in accordance with paragraph (g)(1)(iv) of this section); to

(*ii*) The total remaining OID as of the beginning of the month (as determined under paragraph (g)(1)(v)(A)(*3*) of this section); or

(*2*) In the case of a WHMT holding mortgages issued without OID, the ratio (expressed as a decimal carried to at least eight places) of—

(*i*) The amount of stated interest paid to the WHMT during the month; to

(*ii*) The total amount of stated interest remaining to be paid to the WHMT as of the beginning of the month (as determined under paragraph (g)(1)(v)(A)(*3*) of this section).

(*3*) *Computing the total amount of stated interest remaining to be paid and the total remaining OID at the beginning of a month.* To compute the total amount of stated interest remaining to be paid to the WHMT as of the beginning of the month and the total remaining OID as of the beginning of the month, the trustee must use the prepayment assumption used in pricing the original issue of unit interests.

(B) *Reporting market discount information under the safe harbor following the issuance of final regulations under sections 1272(a)(6)(C)(iii) and 1276(b)(3).* [Reserved.]

(vi) *Reporting bond premium information under the safe harbor.* [Reserved.]

(2) *Use of information provided by a trustee under the safe harbor*—(i) *In general.* If a trustee reports WHMT items in accordance with paragraph (g)(1) of this section, the information provided with respect to those items on the Forms 1099 required to be filed with the IRS under paragraph (d) of this section and on the statement required to be furnished to the TIH under paragraph (e) of this section must be determined as provided in this paragraph (g)(2).

(ii) *Reporting WHMT income, expenses, non pro-rata partial principal payments, and sales and dispositions under the safe harbor.* The amount of each item of income, the amount of each item of expense, and the combined amount of non pro-rata partial principal payments and trust sales proceeds that are attributable to a TIH for each month of the calendar year must be computed as follows:

(A) *Step One: Determine the aggregate of the non pro-rata partial principal payments and trust sales proceeds that are attributable to the TIH for the calendar year.* For each month of the calendar year that a trust interest was held on the record date—

(*1*) *Determine the monthly amounts per trust interest.* The trustee or middleman must determine the aggregate amount of non pro-rata partial principal payments and the trust sales proceeds that are attributable to each trust interest for each month by multiplying—

(*i*) The original face amount of the trust interest; by

(*ii*) The difference between the pool factor for the current month and the pool factor for the following month.

(*2*) *Determine the amount for the calendar year.* The trustee or middleman must multiply the monthly amount per trust interest by the number of trust interests held by the TIH on the record date of each month. The trustee or middleman then must aggregate these monthly amounts, and report the aggregate amount on the Form 1099 filed with the IRS and on the tax information statement furnished to the TIH as trust sales proceeds. No other information is required to be reported to the IRS or the TIH to satisfy the requirements of paragraphs (d) and (e) of this section under this paragraph (g) with respect to sales and dispositions and non pro-rata partial principal payments.

(B) *Step Two: Determine the amount of each item of expense that is attributable to a TIH*—(1) *Determine the monthly amounts per trust interest.* For each month of the calendar year that a trust interest was held on the record date, the trustee or middleman must determine the amount of each item of expense that is attributable to each trust interest by multiplying—

(*i*) The original face amount of the trust interest, divided by 1000; by

(*ii*) The expense factor for that month and that item of expense.

(*2*) *Determine the amount for the calendar year.* The trustee or middleman must multiply the monthly amount of each item of expense per trust interest by the number of trust interests held by the TIH on the record date of each month. The trustee or middleman then must aggregate the monthly amounts for each item of expense to determine the total amount of each item of expense that is attributable to the TIH for the calendar year.

(C) *Step Three: Determine the amount of each item of income that is attributable to the TIH for the calendar year*—(1) *Determine the monthly amounts per trust interest.* For each month of the calendar year that a trust interest was held on the record date, the trustee or middleman must determine the amount of each item of income that is attributable to each trust interest by multiplying—

(*i*) The original face amount of the trust interest, divided by 1,000; by

(*ii*) The income factor for that month and that item of income.

(*2*) *Determine the amount for the calendar year.* The trustee or middleman must multiply the monthly amount of each item of income per trust interest by the number of trust interests held by the TIH on the record date of each month. The trustee or middleman then must aggregate the monthly amounts for each item of income to determine the total amount of each item of income that is attributable to the TIH for the calendar year.

(D) *Definitions for this paragraph (g)(2).* For purposes of this paragraph (g)(2)(ii)—

(*1*) The *record date* is the date used by the WHMT to determine the owner of the trust interest for the purpose of distributing the payment for the month.

(*2*) The *original face amount of the trust interest* is the original principal amount of a trust interest on its issue date.

(iii) *Reporting OID information under the safe harbor.* With respect to each month, trustee or middleman must determine the amount of OID that is attributable to each trust interest held by a TIH by multiplying—

(A) The product of the OID factor multiplied by the original face amount of the trust interest, divided by 1,000; by

(B) The number of days during the month that the TIH held the trust interest.

(iv) *Requirement to provide market discount information under the safe harbor.* The trustee or middleman must provide the market discount information in accordance with paragraph (g)(1)(v) of this section to the TIH in, or with, the written statement required to be furnished to the TIH under paragraph (e) of this section.

(v) *Requirement to provide bond premium information under the safe harbor.* [Reserved]

(3) *Example of safe harbor in paragraph (g)(1) of this section.* The following example illustrates the use of the factors in this paragraph (g) to calculate and provide WHMT information:

Example. (i) *Facts*—(A) *In general. X* is a WHMT. *X*'s start-up date is January 1, 2007. As of that date, *X*'s assets consist of 100 15-year mortgages, each having an unpaid principal balance of $125,000 and a fixed, annual interest rate of 7.25 percent. None of the mortgages were issued with OID. *X*'s TIHs are entitled to monthly, pro-rata distributions of the principal payments received by *X. X*'s TIHs are also entitled to monthly, pro-rata distributions of the interest earned on the mortgages held by *X,* reduced by expenses. Trust interests are issued in increments of $5,000 with a $25,000 minimum. The prepayment assumption used in pricing the original issue of trust interests is six percent. Broker holds a trust interest in *X,* with an original face amount of $25,000, in street name, for *C* during the entire 2007 calendar year.

(B) *Trust events during the 2007 calendar year.* During the 2007 calendar year, *X* collects all interest and principal payments when due and makes all monthly distributions when due. One mortgage is repurchased from *X* in July 2007 for $122,249, the mortgage's unpaid principal balance plus accrued, but unpaid, interest at the time. During November 2007, another mortgage is prepaid in full. *X* earns $80 interest income each month from the temporary investment of X's funds pending distribution to the TIHs. All of *X*'s expenses are affected expenses. The aggregate outstanding principal balance of *X*'s mortgages, *X*'s interest income, and *X*'s expenses, for each month of the 2007 calendar year, along with the aggregate outstanding principal balance of *X* as of January 2008, are as follows:

Month	Principal balance	Income	Expenses
January	$12,500,000	$75,601	$5,288
February	12,461,413	75,368	5,273
March	12,422,593	75,133	5,256
April	12,383,538	74,897	5,240
May	12,344,247	74,660	5,244
June	12,304,719	74,421	5,207
July	12,264,952	74,181	5,191
August	12,102,696	73,200	5,122
September	12,062,849	72,960	5,106
October	12,022,762	72,718	5,089
November	11,982,432	72,474	5,073
December	11,821,234	71,500	5,006
January	11,780,829		

(ii) *Trustee reporting.* (A) Trustee, *X*'s fiduciary, comes within the safe harbor of paragraph (g)(1)(ii) of this section by providing the following information to requesting persons:

Month	Pool factor	Income factor	Expense factor
January	1.00000000	6.04806667	0.42304000
February	0.99691304	6.02941628	0.42184000
March	0.99380744	6.01065328	0.42048000
April	0.99068304	5.99177670	0.41920000
May	0.98753976	5.97278605	0.41952000
June	0.98437752	5.95368085	0.41656000
July	0.98119616	5.93446013	0.41528000
August	0.96821564	5.85603618	0.40976000
September	0.96502792	5.83677704	0.40848000
October	0.96182096	5.81740161	0.40712000
November	0.95859459	5.79790896	0.40584000
December	0.94569875	5.71999659	0.40048000
January	0.94246631		

(B) Trustee determines this information as follows:

(*1*) *Step One: Trustee determines monthly pool factors.* Trustee calculates and provides *X*'s pool factor for each month of the 2007 calendar year. For example, for the month of January 2007 the pool factor is 1.0, which represents the ratio of —

(*i*) The amount that represents the aggregate outstanding principal balance of *X* ($12,500,000) as of the first business day of January; divided by

(*ii*) The amount that represents the aggregate outstanding principal balance of X ($12,500,000) as of the start-up day.

(*2*) *Step Two: Trustee determines monthly expense factors.* Trustee calculates and provides the expense factors for each month of the 2007 calendar year. During 2007, *X* has only affected expenses, and therefore, will have only one expense factor for each month. For example, the expense factor for the month of January 2007 is 0.42304000, which represents the ratio of—

(*i*) The gross amount of expenses paid during January by *X* ($5,288); divided by

(*ii*) The amount that represents the aggregate outstanding principal balance of *X* as of the start-up date ($12,500,000) divided by 1,000 ($12,500).

(*3*) *Step Three: Trustee determines monthly income factors.* Trustee calculates and provides the income factors for each month of the 2007 calendar year. During 2007, *X* has only interest income, and therefore, will have only one income factor for each month. For example, the income factor for the month of January 2007 is 6.04806667, which represents the ratio of—

(*i*) The gross amount of interest income earned by *X* during January ($75,601); divided by

(*ii*) The amount that represents that aggregate outstanding principal balance of X as of the start-up date ($12,500,000), divided by 1,000 ($12,500).

(*4*) *Step Four: Trustee calculates and provides monthly market discount fractions.* Trustee calculates and provides a market discount fraction for each month of the 2007 calendar year using a prepayment assumption of 6% and a stated interest rate of 7.25%.

(*iii*) *Broker's use of the information provided by Trustee.* (A) Broker uses the information provided by Trustee under paragraph (g) of this section to determine that the following trust items are attributable to *C*:

Month	Aggregate trust sales proceeds and non pro-rata partial principal payments	Affected expenses	Gross interest income
January	$77.17	$10.58	$151.20
February	77.64	10.55	150.74
March	78.11	10.51	150.27
April	78.58	10.48	149.79
May	79.06	10.49	149.32
June	79.53	10.41	148.84
July	324.51	10.38	148.36
August	79.69	10.24	146.40

Month	Aggregate trust sales proceeds and non pro-rata partial principal payments	Affected expenses	Gross interest income
September	80.17	10.21	145.92
October	80.66	10.18	145.43
November	322.40	10.15	144.95
December	80.81	10.01	143.00
Total	1438.33	124.19	1774.22

(B) Broker determines this information as follows:

(*1*) *Step One: Broker determines the amount of the non pro-rata partial principal payments and trust sales proceeds received by X that are attributable to C for the 2007 calendar year.* Broker determines the amount of the non pro-rata partial principal payments and trust sales proceeds received by *X* that are attributable to *C* for each month of the 2007 calendar year. For example, for the month of January, Broker determines that the amount of principal receipts and the amount of trust sales proceeds that are attributable to *C* is $77.17. Broker determines this by multiplying the original face amount of *C*'s trust interest ($25,000) by 0.00308696, the difference between the pool factor for January 2007 (1.00000000) and the pool factor for the following month of February 2007 (0.99691304). Broker reports the aggregate of the monthly amounts of non pro-rata partial principal payments and trust sales proceeds that are attributable to *C* for the 2007 calendar year as trust sales proceeds on the Form 1099 filed with the IRS.

(*2*) *Step Two: Broker applies the expense factors provided by Trustee to determine the amount of expenses that are attributable to C for the 2007 calendar year.* Broker determines the amount of *X*'s expenses that are attributable to *C* for each month of the calendar year. For example, for the month of January 2007, Broker determines that the amount of expenses attributable to *C* is $10.58. Broker determines this by multiplying the original face amount of *C*'s trust interest ($25,000), divided by 1,000 ($25) by the expense factor for January 2007 (0.42304000). Broker determines the expenses that are attributable to *C* for the 2007 calendar year by aggregating the monthly amounts.

(*3*) *Step Three: Broker applies the income factors provided by Trustee to determine the amount of gross interest income attributable to C for the 2007 calendar year.* Broker determines the amount of gross interest income that is attributable to *C* for each month of the calendar year. For example, for the month of January 2007, Broker determines that the amount of gross interest income attributable to *C* is $151.20. Broker determines this by multiplying the original face amount of *C*'s trust interest ($25,000), divided by 1,000 ($25), by the income factor for January 2007 (6.04806667). Broker determines the amount of the gross interest income that is attributable to *C* for the 2007 calendar year by aggregating the monthly amounts.

(*4*) *Step Four: Broker provides market discount information to C.* Broker provides *C* with the market discount fractions calculated and provided by the trustee of *X* under paragraph (g)(3)(ii)(D) of this section.

(h) *Requirement that middlemen furnish information to beneficial owners that are exempt recipients and noncalendar-year beneficial owners*—(1) *In general.* A middleman that holds a trust interest on behalf of, or for the account of, either a beneficial owner that is an exempt recipient defined in paragraph (b)(7) of this section or a noncalendar-year beneficial owner, must provide to such beneficial owner, upon request, the information provided by the trustee to the middleman under paragraph (c) of this section.

(2) *Time for providing information.* The middleman must provide the requested information to any beneficial owner making a request under paragraph (h)(1) of this section on or before the later of the 44th day after the close of the calendar year for which the information was requested, or the day that is 28 days after the receipt of the request. A middleman must provide information with respect to a WHFIT holding an interest in another WHFIT, or a WHFIT holding an interest in a REMIC, on or before the later of the 58th day after the close of the calendar year for which the information was requested, or the 42nd day after the receipt of the request.

(3) *Manner of providing information.* The requested information must be provided—

(i) By written statement sent by first class mail to the address provided by the person requesting the information;

(ii) By electronic mail provided that the person requesting the information requests that the middleman furnish the information by electronic mail and the person furnishes an electronic address;

(iii) At an Internet website of the middleman or the trustee, provided that the beneficial owner requesting the information is notified that the requested information is available at the Internet website and is furnished the address of the site; or

(iv) Any other manner agreed to by the middleman and the beneficial owner requesting the information.

(4) *Clearing organization.* A clearing organization described in § 1.163–5(c)(2)(i)(D)(*8*) is not required to furnish information to exempt recipients or non-calendar-year TIHs under this paragraph (h).

(i) [Reserved.]

(j) *Coordination with other information reporting rules.* In general, in cases in which reporting is required for a WHFIT under both this section and subpart B, part III, subchapter A, chapter 61 of the Internal Revenue Code (Sections 6041 through 6050S) (Information Reporting Sections), the reporting rules for WHFITs under this section must be applied. The provisions of the Information Reporting Sections and the regulations thereunder are incorporated into this section as applicable, but only to the extent that such provisions are not inconsistent with the provisions of this section.

(k) *Backup withholding requirements.* Every trustee and middleman required to file a Form 1099 under this section is a payor within the meaning of § 31.3406(a)–2, and must backup withhold as required under section 3406 and any regulations thereunder.

(l) *Penalties for failure to comply.* Every trustee and middleman who fails to comply with the reporting obligations imposed by this section is subject to penalties under sections 6721, 6722, and any other applicable penalty provisions.

(m) *Effective date.* These regulations are applicable January 1, 2007. Trustees must calculate and provide trust information with respect to the 2007 calendar year and all subsequent years consistent with these regulations. Information returns required to be filed with the IRS and the tax information statements required to be furnished to trust interest holders after December 31, 2007 must be consistent with these regulations.

■ **Par. 4.** Section 1.6041–9 is added to read as follows:

§ 1.6041–9 Coordination with reporting rules for widely held fixed investment trusts under § 1.671–5.

See § 1.671–5 for the reporting rules for widely held fixed investment trusts (WHFIT) (as defined under that section). For purposes of section 6041, middlemen and trustees of WHFITs are deemed to have management and oversight functions in connection with payments made by the WHFIT.

■ **Par. 5.** Section 1.6042–5 is added to read as follows:

§ 1.6042–5 Coordination with reporting rules for widely held fixed investment trusts under § 1.671–5.

See § 1.671–5 for the reporting rules for widely held fixed investment trusts (as defined under that section).

■ **Par. 6.** Section 1.6045–1 is amended by adding paragraph (d)(7) to read as follows:

§ 1.6045–1 Returns of information of brokers and barter exchanges.

* * * * *

(d) * * *

(7) *Coordination with reporting rules for widely held fixed investment trusts under § 1.671–5 of this chapter.* See § 1.671–5 for the reporting rules for widely held fixed investment trusts (as defined under that section).

* * * * *

■ **Par. 7.** Section 1.6049–4 is amended by adding paragraph (c)(3) to read as follows:

§ 1.6049–4 Return of information as to interest paid and original issue discount includible in gross income after December 31, 1982.

* * * * *

(c) * * *

(3) *Coordination with reporting rules for widely held fixed investment trusts under § 1.671–5 of this chapter.* See § 1.671–5 for the reporting rules for widely held fixed investment trusts (as defined under that section).

* * * * *

■ **Par. 8.** In § 1.6049–5, paragraph (a)(6) is revised to read as follows:

§ 1.6049–5 Interest and original issue discount subject to reporting after December 31, 1982.

(a) * * *

(6) Interest paid on amounts held by investment companies as defined in section 3 of the Investment Company Act (15 U.S.C. section 80–a) and on amounts paid on pooled funds or trusts. The interest to be reported with respect to a widely held fixed investment trust, as defined in § 1.671–5(b)(22), shall be the interest earned on the assets held by the trust. See § 1.671–5 for the reporting rules for widely held fixed investment trusts (as defined under that section).

* * * * *

■ **Par. 9.** Section 1.6050N–2 is added to read as follows:

§ 1.6050N–2 Coordination with reporting rules for widely held fixed investment trusts under § 1.671–5.

See § 1.671–5 for the reporting rules for widely held fixed investment trusts (as defined under that section).

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 10.** The authority citation for part 301 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 11.** Section 301.6109–1 is amended by:

■ 1. Revising the heading to paragraph (a)(2).

■ 2. Revising paragraph (a)(2)(i).

The revisions read as follows:

§ 301.6109–1 Identifying numbers.

(a) * * *

(2) *A trust that is treated as owned by one or more persons pursuant to sections 671 through 678*—(i) *Obtaining a taxpayer identification number*—(A) *General rule.* Unless the exception in paragraph (a)(2)(i)(B) of this section applies, a trust that is treated as owned by one or more persons under sections 671 through 678 must obtain a taxpayer identification number as provided in paragraph (d)(2) of this section.

(B) *Exception for a trust all of which is treated as owned by one grantor or one other person and that reports under § 1.671–4(b)(2)(i)(A) of this chapter.* A trust that is treated as owned by one grantor or one other person under sections 671 through 678 need not obtain a taxpayer identification number, provided the trust reports pursuant to § 1.671–4(b)(2)(i)(A) of this chapter. The trustee must obtain a taxpayer identification number as provided in paragraph (d)(2) of this section for the first taxable year that the trust is no longer owned by one grantor or one other person or for the first taxable year that the trust does not report pursuant to § 1.671–4(b)(2)(i)(A) of this chapter.

* * * * *

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 12.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 13.** In § 602.101, paragraph (b) is amended by adding an entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.671–5	1545–1540
* * * * *	

Approved: January 5, 2006.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Eric Solomon,

Acting Deputy Assistant Secretary.

[FR Doc. 06–396 Filed 1–23–06; 8:45 am]

BILLING CODE 4830–01–U

Federal Register

Tuesday,
January 24, 2006

Part IV

Department of Labor

Establishment of the Emergency Management Center (EMC) and the Comprehensive Emergency Management Program (CEMP); Notice

DEPARTMENT OF LABOR

Office of the Secretary

[Secretary's Order 01–2006]

Establishment of the Emergency Management Center (EMC) and the Comprehensive Emergency Management Program (CEMP)

1. *Purpose.* The Department of Labor (DOL), through this Order, addresses the continuity of Departmental missions under all operating conditions and DOL's roles and responsibilities in the National, homeland, and economic security arenas. DOL will formulate plans and establish preparedness programs to assure its capability to carry out its assigned functions during a period of national emergency and to maintain Continuity of Operations (COOP) and Continuity of Government (COG). In addition, this Order formally establishes, within the Office of the Assistant Secretary for Administration and Management (OASAM), the Emergency Management Center, which oversees DOL's Comprehensive Emergency Management Program (CEMP). The CEMP shall consist of the following programs and structures to coordinate DOL capabilities, and ensure DOL's ability to carry out its missions under any and all circumstances:

- Continuity of Government.
- Continuity of Operations.
- Communications Security.
- Operations Security.

The CEMP provides the framework for coordination, planning, governance and resource allocation thus enabling DOL to fulfill its roles under all relevant Federal authorities.

2. *Authorities and Directives Affected.* A. *Authorities.* This Order is issued pursuant to the authorities listed in Appendix A.

B. *Directives Affected.* This Order supersedes and cancels Secretary's Order 14–76, ''Alerting System for National Emergency'' (June 1, 1976), and Secretary's Order 23–76, ''Emergency Preparedness and Disaster Relief Functions'' (November 18, 1976).

3. *Scope.* This Order applies to all Department personnel, organizational components and activities.

4. *Establishment of the Emergency Management Center.* The Emergency Management Center (EMC) is established within OASAM. The Emergency Operations Center and all emergency management programs will be directed from the EMC. EMC oversees the CEMP and coordinates Departmental roles and responsibilities to adequately prepare for and respond to a full spectrum of potential natural or man-made disasters, as well as supporting lead Federal agencies in assisting state and local governments, to include international requests for U.S. assistance, to the extent permitted by law, in the event of such disasters.

5. *Delegation of Authority and Assignment of Responsibilities.* A. *The Deputy Secretary of Labor* is delegated authority and assigned responsibility for:

(1) Assuring Departmental support to broader Federal government planning, preparedness, mitigation, response, and recovery efforts under the National Response Plan;

(2) Establishing DOL-wide procedures and permanent or ad hoc workgroups, as appropriate, to study and/or implement activities and projects to address needs determined through Departmental communication and coordination with other Federal agencies, private sector entities, state, local and tribal authorities, and the public, or that develop through incidents of national significance; and

(3) Performing, or delegating as appropriate, any additional or similar duties that may be assigned by the Secretary.

B. *The Assistant Secretary for Administration and Management* (ASAM) is delegated authority and assigned responsibility for:

(1) Developing, establishing and directing the dissemination of standards, procedures, and instructions relating to CEMP, and regularly evaluating Departmental performance measures to assess the readiness of emergency management-related programs;

(2) Directing the design of a management information system that collects and processes all information needs to fully effectuate CEMP, and the maintenance of redundant telecommunications and network infrastructure as necessary for coordination of emergency management operations;

(3) Coordinating all disaster and emergency management investments, including incident management or emergency management systems through e-Gov initiatives, so that they comply with the applicable federal interoperability standards;

(4) Establishing a process within DOL to ensure that acquisitions and activities related to incident/emergency management are coordinated with the ASAM or his designee;

(5) Through the EMC, ensuring (A) the integration and coordination of emergency management-related functions and personnel, including directing the management of security and emergency management programs before, during, and following emergencies; (B) program continuity and guidance on emergency preparedness; (C) development and maintenance of an alerting system and an overall regional emergency plan; (D) conduct of liaison activities with Federal agencies involved in preparedness planning; and (E) provision of regular information regarding all such activities to the ASAM or his designee; and

(6) Performing, or delegating as appropriate, any additional or similar duties that may be assigned by the Secretary.

C. *The Assistant Secretary for Public Affairs* is delegated authority and assigned responsibility for developing, coordinating, and disseminating all DOL public information during emergency activities and developing and maintaining the Departmental Crisis Communications Plan, consistent with other delegations.

D. *The Assistant Secretary for Congressional and Intergovernmental Affairs* is delegated authority and assigned responsibility, consistent with other delegations, to receive requests and inquiries from congressional, state and local agencies relating to emergency management related matters, to communicate all such requests and inquiries to the EMC and such DOL officials as may be appropriate, and to coordinate responses back to all such congressional, state and local agencies. The Assistant Secretary for Congressional and Intergovernmental Affairs shall designate a liaison to the EMC.

E. *The Assistant Secretary for Occupational Safety and Health* is delegated authority and assigned responsibility to ensure the Occupational Safety and Health-specific CEMP and National Response Plan activities are carried out by providing safety and health advice, technical assistance, and follow-on enforcement as appropriate in emergencies; and supporting Federal, state, and/or local authorities' efforts when determining if conditions are safe and healthy for human entry or occupation, consistent with other delegations.

F. *The Assistant Secretary for Employment and Training* is delegated authority and assigned responsibility, consistent with other delegations, for:

(1) Ensuring that the Employment and Training Administration-specific CEMP activities are carried out by assisting in achieving maximum emergency utilization of the civilian workforce, such as the Job Corps, and unemployment assistance programs and

through job training and recruiting activities; and

(2) Providing overall supervision and guidance in the development and coordination of programs and plans for achieving maximum utilization of civilian manpower resources.

G. *The Assistant Secretary for Employment Standards* is delegated authority and assigned responsibility, consistent with other delegations, for:

(1) Ensuring that the Employment Standards Administration-specific CEMP activities are carried out;

(2) Providing overall supervision and guidance in the development and coordination of programs and plans for administering the wage and salary stabilization and labor disputes program.

H. *The Assistant Secretary for Mine Safety and Health* is delegated authority and assigned responsibility, consistent with other delegations, for ensuring the Mine Safety and Health Administration-specific CEMP activities are carried out by advising and assisting in unique emergency situations that require locating and rescuing individuals trapped underground or in a mass of debris, to include developing and maintaining plans and facility readiness for the use of the National Mine Health and Safety Academy as part of Departmental COOP.

I. *The Assistant Secretary for Disability Employment Policy* is delegated authority and assigned responsibility, consistent with other delegations, for ensuring that the Office of Disability Employment Policy-specific CEMP activities are carried out by ensuring that emergency preparedness plans adequately address people with disabilities in the workforce.

J. *The Assistant Secretary for Veterans Employment and Training* is delegated authority and assigned responsibility to assure veterans' employment and training service-specific CEMP activities are carried out by ensuring that emergency preparedness plans address the requirements and needs of veterans and disabled veterans in the workforce.

K. *The Commissioner for Labor Statistics* is delegated authority and assigned responsibility, consistent with other delegations, for providing overall supervision and guidance in the development and coordination of programs and plans for gathering economic data (e.g., employment, unemployment, prices, productivity, wages, and earnings) as are necessary for the administration of economic stabilization measures during an emergency and for the appraisal of the impact of proposed economic stabilization measures and develops plans and programs to carry out damage assessments and data system programs.

L. *The Solicitor of Labor* is delegated authority and assigned responsibility for providing legal advice and counsel to the DOL agencies and offices on all matters arising in the administration of this Order.

M. *All Agency Heads* are delegated the authority and assigned responsibility for:

(1) Developing and maintaining emergency plans necessary to carry out the essential functions of their agency in the National Office and the Field, consistent with the requirements of critical infrastructure protection (CIP), COOP, and COG, and coordinating such plans with the EMC and other departments and agencies, as appropriate;

(2) Providing the necessary funds and staff support to carry out the program responsibilities assigned herein;

(3) Coordinating all disaster and emergency management investments, including incident management or emergency management systems through e-Gov initiatives, with OASAM through the EMC to ensure compliance with the applicable federal interoperability standards; and

(4) Coordinating communications relating to emergency management with congressional, state and local agencies through the Office of Congressional and Intergovernmental Affairs, in coordination with the EMC.

6. *Reservations of Authority and Responsibility.* A. The submission of reports and recommendations to the President and Congress is reserved to the Secretary.

B. This Secretary's Order does not affect the authorities and responsibilities of the Office of Inspector General under the Inspector General Act of 1978, as amended, or under Secretary's Order 2–90 (January 31, 1990).

C. This Secretary's Order does not affect the Order of Succession for Executive Continuity as provided by Secretary's Order 4–2003 (October 14, 2004).

D. Heads of DOL Agencies charged with direct responsibility for program operations exercise the same authority for these programs during emergencies as currently delegated during normal operations.

7. *Re-delegation of Authority.* Unless identified as non-delegable under this Order, authorities delegated within this Order may be re-delegated, provided, however, that re-delegation shall in no way diminish the delegating official's responsibility.

8. *Effective Date.* This Order is effective immediately.

Dated: January 17, 2006.

Elaine L. Chao,

Secretary of Labor.

Appendix A: Authorities

This Order is issued pursuant to:

- 5 U.S.C. 301.
- 6 U.S.C. 101.
- 42 U.S.C. 5195.
- 36 CFR 1236, ''Management of Vital Records'' (July 1, 1998).
- 41 CFR 101–2, ''Occupant Emergency Program'' (July 1, 1998).
- The Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended by Public Law 106–390 (October 30, 2000).
- Homeland Security Presidential Directive 8, ''National Preparedness'' (December 17, 2003).
- Homeland Security Presidential Directive 7, ''Critical Infrastructure Identification, Prioritization, and Protection'' (December 17, 2003).
- Homeland Security Presidential Directive 5, ''Management of Domestic Incidents'' (February 23, 2003).
- Homeland Security Presidential Directive 3, ''Homeland Security Advisory System'' (March 11, 2002).
- Executive Order 12345, ''Providing an Order of Succession within the Department of Labor'' (December 18, 2001).
- Executive Order 13231, ''Critical Infrastructure Protection in the Information Age'' (October 16, 2001).
- Executive Order 13228, ''Establishing the Office of Homeland Security and the Homeland Security Council'' (October 12, 2001).
- Executive Order 12958 as amended, ''Classified National Security Information'' (March 25, 2003).
- Executive Order 12919, ''National Defense Industrial Resources Preparedness'' (June 3, 1994).
- Executive Order 12656, ''Assignment of Emergency Preparedness Responsibilities'' (November 18, 1988).
- Executive Order 12472, ''Assignment of National Security and Emergency Preparedness Telecommunications Functions'' (April 3, 1984).
- Executive Order 12148, ''Federal Emergency Management'' (July 20, 1979).
- National Security Presidential Directive 1, ''Organization of the National Security Council System'' (February 13, 2001).
- Federal Preparedness Circular 65, ''Federal Executive Branch Continuity of Operations'' (June 15, 2004).
- Presidential Decision Directive 67, ''Enduring Constitutional Government and Continuity of Government Operations'' (October 21, 1998).
- Presidential Decision Directive 62, ''Combating Terrorism'' (May 22, 1998).
- The Initial National Response Plan (October 10, 2003).
- The National Incident Management System (March 1, 2004).
- Deputy Secretary of Labor Memorandum, ''Department of Labor, Homeland Security

Advisory System/Protective Measures''
(September 18, 2002).

[FR Doc. 06–619 Filed 1–23–06; 8:45 am]

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Federal Register

Tuesday,
January 24, 2006

Part V

Department of Labor

Management of United States Government Accountability Office Reports; Notice

DEPARTMENT OF LABOR

Office of the Secretary

[Secretary's Order 02–2006]

Management of United States Government Accountability Office Reports

1. *Purpose.* To delegate authority and assign overall responsibility for coordinating, reviewing, and processing United States Government Accountability Office (GAO) reports.

2. *Authority.* This Order is issued under the authority of 5 U.S.C. 301 (Departmental Regulations); 29 U.S.C. 551 (Establishment of Department: Secretary; Seal); Reorganization Plan No. 6 of 1950 (5 U.S.C. Appendix 1); 31 U.S.C. 720 (Government Accountability Office, Agency Reports); and OMB Circular A–50 (Audit Followup).

3. *Redelegations/Transfers of Authority.* Unless provided otherwise in this or another Secretary's Order, the authority delegated in this Order may be redelegated or transferred, as permitted by law or regulation.

4. *Reservation of Authority.* The submission of reports and recommendations to the President and the Congress concerning the administration of statutory or administrative provisions is reserved to the Secretary.

5. *Directives Affected.* Secretary's Order 04–1992 is canceled. This Secretary's Order does not affect the authorities and responsibilities of the Office of the Inspector General under the Inspector General Act of 1978, as amended, or under Secretary's Order 2–90 (January 31, 1990).

6. *Background.* Title 31, Chapter 7 of the United States Code establishes GAO as an independent instrumentality of the U.S. Government independent of executive departments, and sets forth the duties and powers of its head, the Comptroller General. Among these duties is the responsibility to investigate the use of public money. Federal agencies are charged with giving the Comptroller General specified information and permitting GAO inspection of agency records. In addition, GAO evaluates programs and activities of the U.S. Government. 31 U.S.C. 719 directs the Comptroller General to report to Congress on agency expenditures, contracts, administrative controls, and the status of fiscal accounts. 31 U.S.C. 720 requires that following issuance of a GAO report that contains recommendations to the head of an agency, the agency must submit a written statement to the Senate Committee on Homeland Security and Governmental Affairs, the House Committee on Government Reform, the Committees on Appropriations of the Senate and the House and GAO indicating the action taken by the agency on the recommendations. Office of Management and Budget (OMB) Circular A–50, Audit Followup, revised September 29, 1982, provides policies and procedures for use by executive agencies when considering reports issued by GAO where follow-up is necessary. OMB Circular A–50 also specifies those GAO reports for which agency heads will submit statements to OMB.

7. *Scope.* These delegations apply to draft and final GAO reports as well as to related correspondence addressed to the Secretary of Labor or other DOL official.

8. *Policy.* Findings, recommendations, or suggestions presented to the Department in a GAO report will be given prompt and careful consideration. DOL agency heads must act promptly on all recommendations that merit action. The action agency will comment on the findings in a GAO report indicating whether the recommendations will be adopted, considered further, or have been found to be unacceptable. Comments indicating agreement must include planned corrective actions and, where appropriate, dates for implementing these actions. If the recommendations are found to be unacceptable, the reasons for disagreement shall be fully explained.

9. *Delegation of Authority and Assignment of Responsibilities.*

A. The Chief Financial Officer (CFO) is delegated overall authority and assigned responsibility for the GAO reports and will:

(1) Act as the DOL control official for all GAO audits, studies, and reports and all correspondence received from the Congress and other governmental agencies relating to such GAO matters.

(2) Serve as the GAO Liaison and point of contact for all GAO audits and studies (hereinafter, ''reviews'').

(3) Review and approve, or disapprove, all written comments on draft and final GAO reports.

(4) Resolve all disagreements that may arise between DOL agencies regarding responses to GAO reports, both draft and final.

(5) Act as DOL's liaison to other Federal agencies for GAO report matters.

(6) Notify appropriate DOL agencies of planned GAO work.

(7) Designate action agencies to prepare responses to GAO reports and stipulate the deadline required for such responses.

(8) Maintain liaison with GAO concerning all reports and responses.

(9) Provide oversight of DOL's responses to GAO reports, both draft and final, monitor DOL's implementation of accepted recommendations, and provide periodic reports to the Deputy Secretary.

(10) Provide advice and assistance to agency heads with regard to GAO findings, recommendations, or suggestions involving internal control, accounting, and financial policies and procedures.

(11) Establish policies and procedures for DOL's responses to GAO reviews and reports.

(12) Apprise the Deputy Secretary on a quarterly basis, or as designated by the Deputy Secretary, of active GAO reviews and reports relating to the Department.

B. DOL Agency Heads will:

(1) Expeditiously review and comment on GAO's findings and recommendations, and submit prepared responses to OCFO for final clearance through the Executive Secretariat.

(2) Establish sufficient controls to ensure the prompt preparation of comments to be furnished to Congressional committees, OMB, GAO, and implementation of recommendations that merit action.

(3) Designate an individual within the agency to serve as the central contact for the CFO regarding GAO review and report activities and related matters.

(4) Direct all communications received from the GAO, Congress, or other government agencies pertaining to GAO reports to the attention of the CFO.

(5) Ensure that appropriate departmental clearances on responses to GAO reports are obtained, including coordinating with SOL to obtain OMB clearances. Items found at issue during the response clearance phase will promptly be brought to the attention of the CFO for resolution.

(6) Ensure that appropriate GAO responses with the agency heads' signature reach Congressional committees, OMB, and GAO within mandated time frames.

C. The Solicitor of Labor is delegated authority and assigned responsibility to:

(1) Provide legal advice and assistance to all officials of the Department relating to the authorities of this Order.

(2) Review proposed agency submissions of records and responses.

10. *Effective Date.* This Order is effective immediately.

Dated: January 17, 2006.

Elaine L. Chao,

Secretary of Labor.

[FR Doc. 06–618 Filed 1–23–06; 8:45 am]

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Federal Register

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FEDERAL REGISTER PAGES AND DATE, JANUARY

1–230 3
231–536 4
537–872 5
873–1388 6
1389–1472 9
1473–1682 10
1683–1914 11
1915–2134 12
2135–2452 13
2453–2856 17
2857–2990 18
2991–3204 19
3205–3408 20
3409–3752 23
3753–4032 24

CFR PARTS AFFECTED DURING JANUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
6867 (See: Notice of January 10, 2006) 2133
7757 (See: Notice of January 10, 2006) 2133
7973 3199
7974 3201

Executive Orders:
12947 (See Notice of January 18, 2006) 3407
13099 (See Notice of January 18, 2006) 3407
13395 3203

Administrative Orders:
Memorandums:
Memorandum of December 15, 2005 1467
Presidential Determinations:
No. 2006–6 of December 22, 2005 1469
No. 2006–7 of December 30, 2005 871
No. 2006–8 of December 30, 2005 1471
Notices:
Notice of January 6, 2006 1681
Notice of January 10, 2006 2133
Notice of January 18, 2006 3407

5 CFR

337 3409
1650 1389

Proposed Rules:
1651 1984

7 CFR

226 1
400 2135
930 1915
946 1919
982 1921
1740 3205

Proposed Rules:
56 2168
70 2168
319 1700
1000 545
1001 545
1005 545
1006 545
1007 545
1030 545
1032 545
1033 ..... 545, 3435
1124 545
1126 545
1131 545
1493 3790
1496 3442

9 CFR

78 2991
317 1683
381 1683
391 2135
590 2135
592 2135

Proposed Rules:
77 1985
318 2483
381 2483
392 1988
439 2483

10 CFR

35 1926

Proposed Rules:
20 29
30 ..... 29, 275
31 ..... 29, 275
32 ..... 29, 275
33 29
35 29
73 3791
150 275

12 CFR

205 ..... 1473, 1638

Proposed Rules:
Ch. I 287
Ch. II 287
Ch. III 287
Ch. V 287
611 1704

14 CFR

11 1483
21 534
23 ..... 537, 1926, 2143
25 ..... 1485, 3753
36 530
39 ..... 231, 873, 1390, 1930, 1935, 1937, 1939, 1941, 1947, 1949, 1951, 2453, 2455, 2857, 2859, 2993, 2995, 3209, 3210, 3212, 3214, 3216, 3754, 3757
71 ..... 537, 2145, 2997, 2998, 3759, 3760, 3761
73 2146
95 2998
97 ..... 1393, 1686
121 ..... 534, 1666, 1688
135 534

Proposed Rules:
39 ..... 291, 293, 295, 297, 299,

1718, 2491, 3021, 3023, 3248, 3792
71 .....552, 889, 1397, 1398, 3794

15 CFR

930.....788

17 CFR

36.....1953
37.....1953
38.....1953
39.....1953
40.....1953
242.....232
Proposed Rules:
4.....1463

18 CFR

11.....2863
2.....1348
33.....1348
Proposed Rules:
35.....303
370.....303

19 CFR

12.....3000
101.....2457

20 CFR

404 .....2312, 2871, 3217
416.....2871, 3217

21 CFR

201.....3922
210.....2458
314.....3922
510.....875, 2147
520.....875
522.....1689
558.....5, 1689
601.....3922
803.....1488
Proposed Rules:
56.....2493
210.....2494
310.....2309
866.....1399

22 CFR

122.....3762
129.....3762

23 CFR

Proposed Rules:
1313.....29

24 CFR

401.....2112
402.....2112
Proposed Rules:
401.....2126
402.....2126
1000.....2176

25 CFR

243.....2426

26 CFR

1 .....6, 11, 1971, 2462, 4002
20.....2147
31.....11
301.....3219, 4002
602.....6, 4002
Proposed Rules:
1.....2496
31.....46
301 .....2497, 2498, 3248

27 CFR

Proposed Rules:
9.....1500

28 CFR

16.....16
105.....1690
Proposed Rules:
61.....3248

29 CFR

1926.....2879
1952.....2885
2520.....1904
4022.....2147
4044.....2147, 2148
Proposed Rules:
2700.....553
2704.....553
2705.....553

30 CFR

48.....3613
946.....1488

31 CFR

103.....496
215.....2149
501.....1971
Proposed Rules:
103.....516
501.....1994

32 CFR

199.....1695
Proposed Rules:
153.....3254

33 CFR

110.....3001
117 .....1494, 2151, 3763
165 .....538, 2152, 2886, 3003, 3005, 3007
Proposed Rules:
110.....3025
117.....2176
165.....3027, 3442
207.....3446

36 CFR

223 .....522, 523, 3409
1011.....2109
Proposed Rules:
219.....307

37 CFR

Proposed Rules:
1.....48, 61
2.....2498

38 CFR

17.....2464
21.....1496

39 CFR

111.....1976
3001.....2464

40 CFR

9.....388, 654
16.....232
35.....17
52.....19, 21, 24, 241, 244, 541, 1463, 1696, 3009, 3412, 3764, 3768, 3770, 3773, 3776
60.....2472, 3776
61.....2472
63.....1378
81.....24, 541
86.....2810
141.....388, 654
142.....388, 654
180.....2889
239.....3779
257.....3779
258.....3779
271.....3220
300.....3227
Proposed Rules:
50.....2620
51.....69
52 .....85, 569, 577, 890, 892, 1994, 1996, 2177, 3029, 3795, 3796
53.....2710
58.....2710
60.....2509
61.....2509
63.....1386, 1403
86.....2843
122.....894
180.....901
239.....3797
257.....3797
258.....3797
745.....1588
1604.....309

41 CFR

105.....3781
301–10.....876
Proposed Rules:
60-2.....3374
60-300.....3352

42 CFR

419.....2617
Proposed Rules:
412.....3616
424.....3616

43 CFR

Proposed Rules:
2930.....2899

46 CFR

10.....2154

47 CFR

1.....2167
64.....2895, 3014
73 .....245, 246, 247, 877
Proposed Rules:
20.....3029
54.....1721
73.....312, 313

48 CFR

Ch. 1 .....198, 228, 864, 866
1.....200
2.....208, 211
4.....208
5.....219, 220
6.....219
7.....208, 211
8.....221
9.....219, 227
11.....211, 227
12 .....211, 219, 220
14.....219
16.....211
17.....219
19.....220, 221
22.....219, 864
25 .....219, 221, 223, 224, 227, 864
27.....227
34.....227
37.....211
38.....227
39.....211, 227
42.....200, 221
43.....227
44.....225
46.....200, 227
47.....200
48.....227
50.....227
52 .....200, 208, 219, 221, 224, 225, 226, 227, 864
53.....200
213.....3412
215.....3413
219.....3414
237.....3415
241.....3416, 3418
252.....3415
253.....3412
1631.....3015
1644.....3015
1652.....3015
2401.....2432
2402.....2432
2406.....2432
2408.....2432
2409.....2432
2411.....2432
2413.....2432
2415.....2432
2416.....2432
2419.....2432
2422.....2432
2426.....2432
2432.....2432
2437.....2432
2442.....2432
2446.....2432
2448.....2432
2452.....2432
Proposed Rules:
201.....3446
205.....3446
211.....3446
216.....3446
217.....3446
219.....3446
223.....3446
225.....3446, 3448
228.....3446
232.....3446
236.....3446
237.....3446
242.....3449
252.....3446, 3449
Ch. 8 2342
2404.....2444
2408.....2444
2415.....2444
2437.....2444
2439.....2444

2452 2444
9903 313

49 CFR

71 3228
171 3418
172 3418
173 3418
219 1498
383 ....2897, 3613
384 ....2897, 3613
571 ....877, 3786

Proposed Rules:

192 1504
1105 3030

50 CFR

223 834
224 834
229 1980
299 247
600 27
622 3018
635 ....273, 1395, 3245
648 ....1982, 3016
679 ....1698, 3429

Proposed Rules:

17 ....315, 3158
223 3033
270 3797
660 ....1998, 2510, 3254
679 386

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT JANUARY 24, 2006

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:

Caribbean, Gulf, and South Atlantic fisheries—

Red grouper; published 1-19-06

ENVIRONMENTAL PROTECTION AGENCY

Air quality implementation plans; approval and promulgation; various States:

Indiana; published 11-25-05

Solid waste:

Hazardous waste; identification and listing

Exclusions; published 11-25-05

GENERAL SERVICES ADMINISTRATION

Privacy Act; organizational changes; published 1-24-06

STATE DEPARTMENT

International Traffic in Arms regulations:

Registration fee change; published 1-24-06

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

Airbus; published 12-20-05

Dassault; published 12-20-05

TREASURY DEPARTMENT

Internal Revenue Service

Income taxes:

Widely held fixed investment trusts; reporting requirements; published 1-24-06

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Soybean promotion and research order; comments due by 1-31-06; published 12-2-05 [FR E5-06786]

Spearmint oil produced in—

Far West; comments due by 2-3-06; published 12-5-05 [FR 05-23620]

AGRICULTURE DEPARTMENT

Federal Crop Insurance Corporation

Crop insurance regulations:

Basic provisions; written agreements and use of similar agricultural commodities; comments due by 1-30-06; published 11-30-05 [FR 05-23509]

AGRICULTURE DEPARTMENT

Forest Service

National Forest System land and resource management planning:

2005 planning rule; amendments; comments due by 2-3-06; published 1-4-06 [FR E5-08245]

BLIND OR SEVERELY DISABLED, COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE

Committee for Purchase From People Who Are Blind or Severely Disabled

Javits-Wagner-O'Day (JWOD) Program:

Nonprofit agencies and central nonprofit agencies; governance standards; comments due by 1-31-06; published 12-16-05 [FR E5-07439]

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Accident investigation initiation notice and order to preserve evidence; comments due by 2-3-06; published 1-4-06 [FR E5-08239]

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:

West Coast States and Western Pacific fisheries—

Coastal pelagic species; comments due by 2-1-06; published 1-17-06 [FR E6-00419]

ENERGY DEPARTMENT

Federal Energy Regulatory Commission

Electric utilities (Federal Power Act) and natural gas companies (Natural Gas Act):

Jurisdictional agreements modifications; review standard; comments due by 2-3-06; published 1-4-06 [FR E5-08217]

ENVIRONMENTAL PROTECTION AGENCY

Air programs:

Fuel and fuel additives—

Renewable Fuel Program; 2006 default standard; comments due by 1-30-06; published 12-30-05 [FR 05-24611]

Renewable Fuel Program; 2006 default standard; comments due by 1-30-06; published 12-30-05 [FR 05-24610]

Air quality implementation plans:

Ambient air quality standards, national—

Fine particles; comments due by 1-31-06; published 11-1-05 [FR 05-20455]

Fine particles; hearing; comments due by 1-31-06; published 11-15-05 [FR 05-22694]

Air quality implementation plans; approval and promulgation; various States:

Michigan; comments due by 1-30-06; published 12-29-05 [FR E5-08036]

Montana; comments due by 2-2-06; published 1-3-06 [FR 05-24365]

Tennessee; comments due by 2-2-06; published 1-3-06 [FR 05-24412]

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Hexythiazox; comments due by 1-30-06; published 12-30-05 [FR E5-08037]

HEALTH AND HUMAN SERVICES DEPARTMENT

Quarantine, inspection, and licensing:

Communicable diseases control; comments due by 1-30-06; published 11-30-05 [FR 05-23312]

HOMELAND SECURITY DEPARTMENT

Coast Guard

Drawbridge operations:

Washington; comments due by 2-3-06; published 12-5-05 [FR 05-23637]

Pollution:

Pollution prevention equipment; oil discharge reduction from vessels, and elimination of ozone-depleting solvents in equipment tests; comments due by 2-1-06; published 11-3-05 [FR 05-21573]

INTERIOR DEPARTMENT

Fish and Wildlife Service

Endangered and threatened species:

Critical habitat designations—

California red-legged frog; comments due by 2-1-06; published 11-3-05 [FR 05-21594]

INTERIOR DEPARTMENT

Minerals Management Service

Royalty management:

Federal leases on takes or entitlements basis; reporting and paying royalties; meeting; comments due by 1-30-06; published 11-29-05 [FR 05-23380]

LABOR DEPARTMENT

Occupational Safety and Health Administration

Construction and occupational safety and health standards:

Roll-over protective structures; comments due by 1-30-06; published 12-29-05 [FR 05-24462]

SOCIAL SECURITY ADMINISTRATION

Social security benefits:

Disability benefits; suspension during continuing disability reviews; comments due by 2-3-06; published 12-5-05 [FR 05-23615]

Fugitive felons and probation or parole violators; nonpayment of benefits; comments due by 2-3-06; published 12-5-05 [FR 05-23618]

TRANSPORTATION DEPARTMENT

Air travel; nondiscrimination on basis of disability:

Medical oxygen and portable respiration assistive devices; comments due by 1-30-06; published 10-21-05 [FR 05-21078]

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Air carrier certification and operations:

Transport category airplanes; enhanced airworthiness program for airplane systems and fuel tank safety; comments due by 2-3-06; published 10-6-05 [FR 05-19419]

Airworthiness directives:
BAE Systems (Operations) Ltd.; comments due by 2-3-06; published 1-4-06 [FR E5-08243]
Boeing; comments due by 1-30-06; published 12-15-05 [FR 05-24052]
Empresa Brasileira de Aeronautica S.A. (EMBRAER); comments due by 2-3-06; published 1-4-06 [FR E5-08242]
Eurocopter France; comments due by 2-3-06; published 12-5-05 [FR 05-23602]
Fokker; comments due by 2-3-06; published 1-4-06 [FR E5-08240]
Gulfstream; comments due by 2-3-06; published 1-4-06 [FR E5-08241]
Learjet; comments due by 2-3-06; published 12-5-05 [FR 05-23510]
McCauley Propeller Systems; comments due by 1-30-06; published 11-30-05 [FR 05-23430]
Airworthiness standards:
Special conditions—
Garmin International, Inc.; GFC-700 AFCS on Mooney M20M and M20R airplanes; comments due by 1-30-06; published 12-30-05 [FR 05-24668]
Transport category airplanes—
Airplane performance and handling qualities in icing conditions; comments due by 2-2-06; published 11-4-05 [FR 05-21793]
Class E airspace; comments due by 2-3-06; published 12-20-05 [FR 05-24228]

TRANSPORTATION DEPARTMENT

Federal Highway Administration

Engineering and traffic operations:
Interstate system; highway construction and reconstruction projects; design standards; comments due by 1-30-06; published 11-30-05 [FR 05-23476]

TRANSPORTATION DEPARTMENT

National Highway Traffic Safety Administration

Alcohol-impaired driving prevention programs; incentive grant criteria; comments due by 2-2-06; published 1-3-06 [FR 05-24623]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

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H.R. 4340/P.L. 109–169

United States-Bahrain Free Trade Agreement Implementation Act (Jan. 11, 2006; 119 Stat. 3581)

Last List January 12, 2006

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